UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD

CORE BOARD MEETING

Arlington, Virginia

Monday, November 1, 2010

PARTICIPANTS:

Core Board Members:

WAYNE LEDNAR, M.D., Ph.D.

GREGORY POLAND, M.D.

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NANCY W. DICKEY, M.D.

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JAMES LOCKEY, M.D.

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HONORABLE TOGO WEST

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DR. WILLIAM UMHAU

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A.J. AWAN

LAKIA BROCKENBERRY

CAPTAIN JOYCE CANTRELL

DR. LIMONE COLLINS

DENISE DAILY

STEVEN EBERLY

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Presenters:

COLONEL THOMAS BAKER

WILLIAM HALPERIN, M.D.

DR. JAMES KELLY

CAPTAIN JEFF TIMBY

Court Reporter:

CHRISTINE ALLEN

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P R O C E E D I N G S

(9:02 a.m.)

DR. POLAND: Can we have folks take their seats, please, and we'll get started.

All right. I'd like to welcome everybody to this meeting of the Defense Health Board. We have a number of important and somewhat lengthy topics on our agenda. So, we'll get started.

Ms. Bader, would you call the meeting to order, please?

MS. BADER: Certainly. As the designated federal officer for the Defense Health Board, a federal advisory committee, and a continuing independent scientific advisory body to the Secretary of Defense via the assistant secretary of Defense for Health Affairs and the surgeons general of the military departments, I hereby call this meeting of the Defense Health Board to order.

DR. POLAND: Thank you, Ms. Bader. And carrying on the tradition of our board that I hope

will long outlast any of us individually, I'd like to ask the board to stand for a minute of silence to honor the men and women who serve our country.

(Minute of Silence)

DR. POLAND: Thank you very much. I don't think we realized when we first scheduled this meeting well over a year ago that this would be time to vote. So, I apologize that many of you had to get absentee ballots.

MS. BADER: Yes.

DR. POLAND: If you did that, you may have realized and speak up in your home state, they don't make absentee ballots very easy or user-friendly for the military, the very people who ensure a continuation of our democracy.

Since this is an open session, before we begin, I'd like to go around the table and have the board and distinguished guests introduce themselves, if we can. I'll start to my right, and we'll go around.

MR. WEST: Good morning. I'm Togo West, and I would add on the question on military votes

is new legislation that all the jurisdictions are being required to comply with. It should have a big input, the Move Act. So, we'll see.

GEN MYERS: Dick Myers, core board member, retired military.

DR. ROBB: Dr. Douglas Robb. I'm the new joint staff surgeon. The Pentagon replaced Admiral Smith.

DR. ENNIS: Dr. Frank Ennis. I'm a professor of medicine, molecular genetics, and microbiology at the University of Massachusetts Medical School.

DR. PARISI: I'm Dr. Joe Parisi, a professor of pathology at Mayo Clinic College of Medicine and a consultant in the Department of Pathology there. Also chair of the Subcommittee on Pathology and Laboratory Services for the Defense Health Board.

DR. WALKER: I'm David Walker, chair and professor at the Department of Pathology University of Texas medical branch. I'm still the director of the Center for Bio Defense and

Emerging Infectious Diseases.

DR. DICKEY: Nancy Dickey. I'm president of the Texas A&M Health Science Center and family physician by training.

DR. MASON: I'm Tom Mason, professor of Environmental and Occupational Health, University of South Florida, College of Public Health, Tampa.

DR. O'LEARY: Dennis O'Leary, president emeritus of the Joint Commission.

DR. LUEPKER: So, I'm Russell Luepker, and I'm professor of Epidemiology and Medicine at the University of Minnesota.

DR. KIZER: I'm Dr. Ken Kizer.

CPT COWAN: I'm Alan Cowan. I'm a U.K. liaison, so, I work in the Department of Defense Enforced Health Protection and also in the Department of Veterans' Affairs in the Office of Public Health and Environmental Hazards.

CDR SLAUNWHITE: Good morning. I'm Commander Cathy Slaunwhite, Canadian Forces medical officer, general practitioner by training, and I work in a liaison role at the embassy in

Washington, D.C.

CDR PADGETT: Good morning, Bill Padgett, the Marine Corps liaison.

DR. HACKEY: Wayne Hackey, Health Affairs liaison.

LTC GOULD: Phil Gould, Air Force liaison.

CPT NAITO: Neal Naito, Navy liaison.

CDR SCHWARTZ: Erica Schwartz, Coast Guard liaison.

COL KRUKAR: Good morning. Michael Krukar, director of Military Vaccine Agency.

COL MOTT: Bob Mott. I'm the Army liaison.

CPT TIMBY:: Captain Jeff Timby, I'm the second Marine expeditionary force forward surgeon.

DR. BUTLER: Dr. Frank Butler from the Committee on TCCC.

DR. LEWIS: Frank Lewis, I'm the executive director of the American Board of Surgery.

DR. KAPLAN: Ed Kaplan, professor of

Pediatrics, University of Minnesota Medical School.

DR. SHAMOO: Adil Shamoo, professor, University of Maryland School of Medicine, member of the board, and chair of the Medical Ethics Subcommittee.

DR. CLEMENTS: John Clements, I'm the chair of Microbiology and Immunology and director the Tulane University Center for Infectious Diseases in New Orleans.

DR. LOCKEY: Jim Lockey, professor of Pulmonary Medicine and Environmental Health at the University of Cincinnati.

DR. HALPERIN: Bill Halperin, chair of Preventive Medicine, New Jersey Medical School in Newark, New Jersey, and core board member.

REV CERTAIN: Robert Certain, core board member, Episcopal priest, retired Air Force chaplain.

COL McPHERSON: I'm Joanne McPherson. I'm the executive secretary of the DoD Taskforce on the Prevention of Suicide by Members of the

Armed Forces, holding down the seat for General Volpe until he can arrive later today. Thank you.

MS. BADER: Christine Bader, director of Defense Health Board.

DR. LEDNAR: Wayne Lednar, global chief medical officer of the DuPont Company and co-vice president of the Defense Health Board.

DR. POLAND: And I'm Greg Poland, professor of Medicine and Infectious Diseases at the Mayo Clinic in Rochester, Minnesota, and one of the co-vice presidents.

Maybe we can also start over here and introduce all our guests.

DR. JENKINS: Don Jenkins, chief of Trauma at Mayo Clinic, retired Air Force, member of the Trauma and Injury Subcommittee.

DR. CHAMPION: Howard Champion, professor of Surgery and senior advisor on Trauma and Uniform Services University, and a member of the Injury and Trauma Subcommittee.

DR. UMHAU: William Umhau, Family Medicine, Travel Medicine at Occupational Health

and Safety Services, NSA, Fort Meade.

DCDR DANIEL: Good morning, Chris Daniel, deputy commander at the Army Medical Research and Materiel Command.

MS. DAILY: Good morning. I'm Denise Daily. I'm the executive director for the Defense Taskforce for Wounded Warriors. And what I have here is my staff, and we're kind of RECON-ing your event because we hope to have our first meeting here pretty soon. I'll really quickly run through. Ryan, Phil, Joseph, Lakia, Alan, Larry, and myself, Denise Daily. Thank you.

MAJ LEE: I'm Major Roger Lee. I'm on the Joint Staff, work for the Joint Staff surgeon and the J4 Health Service Support Division.

MR. CRON: Kevin Cron. I'm a preventive medicine resident with RARE.

MS. SIKORSKI: Good morning. I'm Cindy Sikorski, preventive medicine resident, USUHS.

MS. GRANGER: I'm Eldesia Granger, and I'm an internal medicine and pediatric resident from the University of North Carolina, Chapel

Hill.

MR. MILLER: Good morning. I'm Gene Miller from Battelle, retired Army and military.

MR. MALCOLM: I'm Perry Malcolm, a position with the OSD, DDRN&E.

MS. COATES: I'm Marianne Coates. I am a communications consultant to the Defense Health Board, contracted.

COL GRIMES: Good morning. I'm Jamie Grimes. I'm the national director of Defense and Veterans' Brain Injury Center.

LTC CERSOVSKY: Good morning. Steve Cersovsky. I'm the director of Epidemiology and Disease Surveillance at the U.S. Army Public Health Command.

MS. PEABODY: Good morning. I'm Hillary Peabody, and I'm an analyst with the Defense Health Board.

MS. MARTIN: I'm Elizabeth Martin, and I'm also an analyst with the Defense Health Board.

MS. JOVANIC: Good morning. I'm Olivera Jovanic. I'm a senior analyst at the Defense

Health Board and CCSI contractor.

MR. CRETIEN: Jean-Paul Cretien. I'm the two Marine expeditionary force forward preventive medicine officer.

MS. JARRETT: Lisa Jarrett, Defense Health Board staff.

MS. KLEVENOW: Jen Klevenow, DHB support staff.

MS. SCHNESSLER: Brittany Schnessler, DHB support staff and events assistant.

MR. SILVIA: Joe Silva, professor of Medicine and Infectious Diseases, University of California, Davis School of Medicine, and dean emeritus.

DR. POLAND: Mike, we missed you, too. Or you missed us. (Laughter)

DR. PARKINSON: I'm sorry. Mike Parkinson, past president of the American College of Preventive Medicine, now a principal in P3 health, working with employers and hospitals around performance.

DR. POLAND: All right. Thank you. Ms.

Bader has some administrative remarks, and then we'll begin.

MS. BADER: Sure. Good morning again and welcome. I'd like to thank the Key Bridge Marriott for helping with the arrangements for this meeting, and, of course, all of the speakers who have worked hard to prepare their briefings for the board. As well, I'd like to thank the Defense Health Board staff, Jen Klevenow, Lisa Jarrett, Elizabeth Graham, Olivera, and Gene Ward, as well as welcome our new staff, Elizabeth, Hillary, and Brittany, who have joined us here today.

I'd like to ask everyone to please sign the general attendance roster on the table outside of the room if you have not already done so. And for those who are not seated here at the U-shaped table, there are handouts that are provided also outside where you should sign in to the meeting.

Because this is an open session, it is being transcribed, and please be sure that you state your name before you speak and use the

microphone so that our transcriber can accurately record your comments.

We will have a catered working lunch here for board members, ex-officio members, service liaisons, and DHB staff. Lunch will also be provided for speakers and distinguished guests. For those looking for lunch options, the hotel restaurant is open for lunch, as well there are several dining options within walking distance, such as McDonald's, Chipotle, Starbucks, et cetera. And if you need further information, you can ask the concierges down in the lobby.

There is a group dinner tonight, which is scheduled for 6:30 p.m. at Restaurant 3, located at 2950 Clarendon Boulevard in Arlington. The restaurant is only approximately 1.5 miles from the hotel, and the Defense Health Board will be providing shuttle service. The shuttle will leave the hotel at 6:00 p.m. promptly from the hotel lobby, and there will also be a return shuttle service to the hotel. The cost for dinner is $36. Please provide $36 in cash to Jen

Klevenow.

Finally, Mr. Middleton is scheduled to make remarks on our agenda for this morning. Unfortunately, commitments at the Pentagon have prevented him from being here today. He wanted me to send to you his regrets and to thank the board for their hard work in working to promote health and wellbeing for our armed forces and their beneficiaries.

So, with that, I would like to turn the meeting back over to Dr. Poland.

DR. POLAND: I might say, too, Dr. Mike Oxman couldn't be with us today. He is in Italy with his wife on their -- I forgot now -- is it 40 or 45th anniversary or something? We know her as Saint Marcy. (Laughter) And you know Mike well enough, you know what I mean.

Okay, two things. One, we're ahead of time on our agenda because the reason Ms. Bader just mentioned, and one of my goals is to keep us that way. The second is we're going to talk first thing this morning on the proposed revisions to

fluid resuscitation and tactical evacuation.

Let me just tee this up a little bit and say that we divided the question previously, hypothermia and fluid resuscitation at our last meeting and postponed a vote on this. We asked a lot of questions regarding fluid resuscitation. We asked that there be epidemiologic rating of the evidence, and I can tell you because of the two co-vice presidents, I've been the one to help manage or shepherd that question through. How impressed I've been at the amount of time, effort, and resources that have been put into this. They've done exactly as we've asked them to do, and I think you'll see that this morning. My goal is to move through the presentation, give plenty of time for comments and discussion among the board, and then bring this to a vote and resolution.

I also recognize, because many of around the table are internists, and I know our love for data. The reason that this is epidemiologic, we graded, is so that we can see where the data are

high-quality and where they are of lesser quality, but the data are the data, and that's what we have to work with. I know in certain instances you may feel like you'd like to have more, but we simply don't, and I think as we recognize in all of medicine, that data changes over time and these guidelines will change over time as more studies become available.

Dr. Butler did send me a lot of the papers that were used in this and other professional societies' guidelines. I spent about a day going through them. It's been a long time since I've looked at material like that, and I just have to say how impressed I am with the work of this group.

So, with that, I'm going to introduce Captain Jeff Timby. He's currently stationed as a surgeon with the Joint Taskforce Civil Support at Fort Monroe in Virginia. His previous duties included head of Pulmonary Division for Pulmonary Diseases and Critical Care at the Naval Medical Center in Portsmouth; senior medical officer,

Shock Trauma Platoon, Combat Service Support Battalion 22; officer in charge of the Detention Center with the Joint Taskforce Guantanamo; and command surgeon with the Naval Special Warfare Development Group in Dam Neck, Virginia. Captain Timby is an assistant professor of Medicine at USUHS, a position he's held since October of 2002, and a recipient of numerous awards and recognitions, including the Navy Defense Medal, Outstanding Military Volunteer Medal, Navy Marine Corps Commendation Medal, Defense Meritorious Service Medal, July 2001 and June 2004 Bronze Star in the Iraqi Campaign Medal with Marine Combat Unit Insignia. He'll be presented the proposed revisions to fluid resuscitation and tactical evaluation, after which we'll have discussion, and, as I mentioned, a vote.

So, Captain Timby? And his presentation is under Tab 2 in your folder.

CPT TIMBY:: Good morning. Dr. Poland, thank you for that warm introduction.

Let me make a couple of amendments to

that. I'm no longer with the Joint Task Force Civil Support at Fort Monroe. I'm now the second Marine expeditionary force forward, operative word being "forward," surgeon, ready to deploy to Afghanistan in March. So, again, trying to get our ducks in a row to get the leadership or take the leadership role with my commanding general at RC Southwest down in Helmand Province.

So, with that, I'm not sure why I feel nervous now. I guess I should be feeling nervous then. (Laughter)

Anyway, a couple of caveats. Last time I was with the Marines, I came home, and my son said -- that time he was in eighth grade. He said, I like when you're with the Marines, dad. And I think wow, that must be because of my cool hairdo, my buff physique. No, dad, you curse a lot more, is what he said. (Laughter) And so, if I let anything rip, it's only by my environment, and I apologize upfront. I'll try to keep it clean.

Slide, please. The discussion today is

on pre-fluid management of combat injuries. The talk will be broken into three parts basically, and one is how did the guidelines get to where they currently are; then the proposed guideline change and the reasoning for that, and then, thirdly then is a response to a teleconference that we had on October 21 to then address the issues and questions that were raised during that time and, again, to give kind of the feedback information to the board to help to answer those questions that were raised at that time.

There will be a break about two-thirds of the way into it to ask questions. Again, I turn to the board members if we can just get through some of the background information. Then I'll leave a moment before we get into the teleconference issues for any comments that folks want to make.

The initiative began actually back in 1993 as part of a pre-hospital fluid resuscitation discussion as part of the biomedical R&D project listed below. At the time, the ATLS

recommendation was aggressive fluid resuscitation, two liters of fluid in route to the hospital. Usually, those transport times were brief. And, again, I'm guilty of this myself. What some of my residents would actually have referred to as saltwater drowning, we provided a lot of saline, a lot of crystalloid solutions in support of blood pressure, adding pressors and whatnot to the management.

Slide, please. The key premise was that we're not going to ask our corpsman or medics to do anything that we can't provide solid evidence in the literature or at least field experience to say that this is actually prudent and a good thing to do, and we'll save lives on the battlefield. The picture to the bottom right shows our current war-fighter. The medic looks similar to that. They carry about 100 pounds of really light stuff throughout their battle space.

In general, space and cube weight is a critical factor whenever we're talking about adding something to them; you really almost at

this point have to take something away for them to be able to carry it into the field. Again, much of the care that our folks are providing and care under fire, as well as in the tactical field care. It's exactly what is carried on that member's back. They may have a vehicle that may be pinned down in a different position.

So, the majority of the work is done with what this man has carried in on his back. So, again, to ask him to carry more fluid, more materials, more equipment, again, you have to take something away for him to be able to do that.

Slide, please. In the initial research and looking at the R&D project, 17 references state that despite the widespread use, there was little evidence to really support it. And, again, 12 references look at aggressive fluid resuscitation in the setting of an unrepaired vascular injury may actually promote further bleeding and higher mortality.

Slide, please. Again, the beneficial effect of that in the animal studies was largely

done in a controlled hemorrhage type of a model. And so, again, the beneficial effects in that model will differ from those that would be in a uncontrolled hemorrhage.

Slide, please. If you look at combat information, feedback from as far back as World War I, again, aggressive fluid resuscitation prior to the member getting to the operative suite where a hemorrhage can be controlled was generally found to be an unfavorable intervention.

Slide, please. In Kaweski study for 1990, 6,855 patients looking at hypotension as a major predictor for adverse outcomes showed that pre-hospital fluid resuscitation did not necessarily change these numbers when you look at that cohort of patients.

Slide, please. Crawford study of patients with ruptured adnominal aortic aneurisms showed that those patients who had received aggressive fluid resuscitation prior to the operative suite had a survival of about 30 percent. Slide, please. Whereas those who had a

less- aggressive fluid approach had a higher survival rate at 46 percent, provided their blood pressure was maintained somewhere between 50 to 70 mmHG in the ride in. Again, favoring a hypotensive resuscitation approach to management. And so, again, the recommendation in this paper was to withhold aggressive fluid administration prior to the arrival to the operative suite.

Slide, please. The study by Bickell through I think it was University of Houston's Medical Center looked at a cohort of 598 patients. Half received aggressive fluid resuscitation, half received less aggressive fluid resuscitation.

Slide, please. In the folks that received the aggressive fluid resuscitation, there was 62 percent survival, and in that group that received the less- aggressive approach, their survival was actually higher. A lot of things that you could poke in the eye about this particular study, and I've heard a number of folks do that, but, again, the literature in this study seems to suggest that an aggressive fluid

management program may not be the most prudent approach to fluid management. Again, keep in mind that these were patients coming in from a civilian trauma environment transport time is measured in minutes.

If you look at the Battle of Mogadishu, you could take that time in minutes, multiply that into hours, and that's what the actual resuscitation interval pre-hospital intervention that those folks -- and so, this then asks the question, this is common in a lot of the civilian literature: Is this the right answer to the wrong question? Again, is this not necessarily applicable to what our war-fighters, our medics, corps men are experiencing out their in the battlefield?

Slide, please. Animal studies looking at uncontrolled hemorrhage, again, support the aggressive fluid resuscitation is not the way to go, but, again, withholding fluid resuscitation may have a greater benefit, and nine references are cited there.

Slide, please. And if you look at it from just what is our perspective in terms of giving fluids out in the field and then you have a hour later, if it's a crystalloid solution, 1000 CCs of your lactated ringers is quickly redistributed into the interstitial space really even before the Medevac has even arrived. So, again, this is a short-lived intervention in the environment here.

Slide, please. In the typical transport time ranging in 15 to 30 minutes in the civilian environment, again, infusion of a crystalloid solution is probably an acceptable approach to things because 15 minutes later, the fluid will still be where you had put it, and as the member or as the person arrives to the emergency department or the operative suite, then blood products and other fluid interventions can be done. It can then offer a more definitive management, including the surgery.

Slide, please. The first publication of the tactical combat casualty care guidelines was

in 1996, as a supplement to the Military Medicine publication. Slide, please. And in those guidelines published then, IV fluid resuscitation, IVs in general were delayed until the tactical field care. Again, we are not recommending that in a hail of bullets that anybody would be out there on the firing line in the kill zone putting in IVs and delaying the transport of the patient away from the hail of bullets, as well as yourself, but in tactical field care, again, no IV fluids were recommended, and patients were not in shock. In fact, we recommended or Captain Butler recommended that fluids be administered orally in that subgroup. In casualties that had uncontrolled hemorrhage, and that was largely torso or maybe within the groin or in the axila where options for controlling the hemorrhage were somewhat more limited. No IV fluids were recommended in that setting, as well, of uncontrolled hemorrhage.

IV fluids in the form of Hespan, a colloid agent that had a starch, was recommended

initially for casualties who were in shock as a result of hemorrhage, but that hemorrhage has since then been controlled, i.e., extremity hemorrhage that has then be tourniquetted. And so, again, that was the limited use for IV fluids, was in the shocky patient with controlled hemorrhage, and that fluid intervention was limited to 1,500 CCs.

Slide, please. This was my first lesson in the trapdoor, spider techniques of Captain Frank Butler. I happened to be walking in the hallway out in front of his office as I overheard Frank, oh, I'm really disappointed you won't be able to make the meeting, but I think I may have an alternative. Jeff, come here. And I come walking in, and that's when I got invited to be the leadoff speaker for this, or not leadoff, but I ended up with the discussion of casualty number one in this symposium. But the Special Operations Medical Association meeting in 1999 outlined casualties or clusters of casualties that occurred during the Battle of Mogadishu, and then asked the

question: Applying the care under fire tactical field care and evacuation care, tactical evacuation phases of care, what intervention would you recommend and what literature supports that?

Slide, please. And then fluid resuscitation, there was a clear consensus among the panel members that if a casualty even with an uncontrolled hemorrhage situation was hemorrhaging to the point or had developed a shock state significant enough that they then had an altered mental status, that that person should be fluid resuscitated, trying to maintain them long enough to be able to get them into surgical hands. And, again, the emphasis was not on trying to aggressively administer fluids, but to administer just enough fluids to achieve a hypotensive resuscitation with systolic pressures in the 80 to 90 range and not trying to achieve normal blood pressure, where, again, a pressure had, especially in the phase of coagulopathy, hyperthermia, may actually pop the clot off of the vascular injury and result in extensive further bleeding.

Slide, please. The Joint MRMC-ONR Fluid Resuscitation Conference held in 2001, 2002, co-chaired by Dr. John Holcomb and Dr. Howard Champion, revealed or produced a fluid resuscitation strategy that has since been largely employed into the current guidelines. And with that, the assessment for hemorrhagic shock being altered mental status in the absence of a head injury and a weak or absent peripheral pulse being the best indicators for shock in the field. And that, again, if you go down through, no fluids are necessary if the member is not in shock, and, again, permissible to deliver PO fluids, even in the face of an abdominal wound, provided the member is able to take it without pain or further nausea or vomiting.

Slide, please. Fluid resuscitation in those in shock, Hextend was now recommended because of the lesser coagulopathic affect of Hextend versus Hespan, again, 500 CC initial bolus to be repeated after 30 minutes of still in shock, and then the Hextend, 1,000 CCs of Hextend was the

recommended peak.

Slide, please. This was carried into the PHTLS Manual and the chapters on tactical combat casualty care, and then ultimately the sixth edition with the green edition, it is largely the training manual that we use in the Department of Defense currently. The PHTLS recommendations are endorsed by the American College of Surgeons' Committee on Trauma, as well as the NAEMT, which is the certifying organization for all paramedics going out into the field. And, again, it's widely used and is really the document of educational use for the Department of Defense for pre-hospital resuscitation.

Slide, please. The current fluid resuscitation guidelines are as you see them now, and they largely effect what we just went through in terms of the discussion. And this, again, note is in the tactical field care portion of the guidelines. And with this, we assess for hemorrhagic shock using altered mental status, weak or absent peripheral pulse are the best

indicators for shock in the field. The same caveats for if the member is not in shock. If the member is in shock, again, the same as had been developed in the 2003 conference.

This letter C, subheading C is very important. When you're in a tactical field environment, again, the resources that are available for the medic or corpsman to deliver to his casualty or limited by that which he carries on his back or is spread-loaded across the force continued efforts to resuscitate any one individual really needs to be weighed against the logistical and tactical considerations of further casualties. Is this a one of one casualty? Does he have more casualties? Are you still under fire? Are they likely to come under more fire prior to the evacuation of this particular casualty, as well as the unit in general?

So, that the corpsman and medic are not only making medical decisions, they're also making these life and death decisions of do I use everything that I've got in my pack on this one

man or am I likely not going to benefit another one of my service members who may have a better chance of surviving? And so, this decision-making capacity or decision-making responsibility for our corpsmen and medics is really an onerous one, too, then, and a lot of the medics and corpsmen have come back to me saying boy, that was not an easy decision to make. Why did you do it that way? Well, it seemed like it was the right thing to do was usually about the best answer they can come back with.

Now, way down here, buried at the bottom is the discussion well, what if the member does have a head injury, what do we use then? And in this, it is if a casualty with TBI is unconscious and has no peripheral pulse, resuscitate to restore the radial pulse, which should bring us to a blood pressure at least in the 85, maybe 90 mmHg range.

Slide, please. Now we're in the tactical evacuation care. Again, these are the guidelines as they are currently published. We

are now reassessing for hemorrhagic shock using the same methods as before. No change in the no-shock subgroup. If in shock, again, not really a change from the tactical field care side. Here, because the member is now in the evacuation phase of care, the resources available are usually more robust.

Now, this may be an evacuation on back of a fast boat, this may be an evacuation in the back of a truck, this may be an evacuation in a place where resources are not that readily available, but, again, in a large part of the evacuations as folks are leaving the battlefield, it's either in an ambulance or in a helicopter that is equipped to be able to provide medical resources. And, again, if those resources are available, they continue resuscitation. And, again, if blood products are available, to use those first, Hextend, Lactated Ringers, whatever is needed, again, to support the member or support the casualty until they arrive back at a treatment facility. And, again, no real difference in the

traumatic brain-injured patient relative to the guidelines for tactical field care.

Slide, please. As we entered into the discussion for changing the current guidelines, these were some of the deceived deficiencies, is that the guidelines, as they stand now, don't necessarily call for the use of blood pressure or to give a target for that blood pressure if a sphygmomanometer or some other device, monitor of some device is available to be able to provide that. And, again, we want to give the transport medic and corpsman the opportunity to know what their target blood pressure range is.

Also, though we did mention Packed Red Blood Cell administration in the casualty evacuation phase, it does not reflect the current one-to-one ratio of plasma to blood in the guideline as it speaks now.

It calls for Hextend to be used initially instead of plasma and packed red blood cells when packed red cells and plasma may be available.

And then, lastly, the decision for fluid resuscitation for the traumatic brain-injured patient, you use both mental status as well as absent or diminished radial pulse as a measure. And, again, the full spectrum of mental status alterations may be present for those members with traumatic brain injury, and I felt that it needed to be removed as a measure by which fluid resuscitation guidance should be offered.

Slide, please. And so, in red are the guideline revision proposals. One that if blood pressure monitoring is available on your tactical evacuation, again, this is in tactical evacuation phase, if blood pressure monitoring is available to use the target between the 80 and 90 mmHg, again, using that hypotensive resuscitation philosophy.

No change in the patient without shock. If in shock and blood products are not available. So, again, what we tried to do here is try to break out if blood products are available or blood products are not available. So, in this

situation, blood products are not available. Again, used Hextend as our primary fluid administration agent, repeat in 30 minutes if the patient is still in shock, assuming that this is still the measure by which they will be using it, and to continue resuscitation with Hextend crystalloid or crystalloid solution as needed to maintain the target blood pressure or the clinical improvement in the mental status.

Again, if you note, we did not continue with the recommendation to limit the fluid volume of resuscitation of Hextend because in the review of the literature that we had available to review, the 1,500 or 1,000 CCs of hetastarch really was not supported by the literature that we had available to us to review. So, we removed that limitation.

Slide, please. And then the caveat now is the blood products now are available, and, again, it is under an approved command or theatre protocol, and so, that takes a lot of the weight of having to add a lot of burden of other

guideline requirements because those will be under that super heading, if you will, for any use of blood products in a evacuation platform. And that we recommended that the resuscitation begin with two units of plasma, followed by packed red blood cells, again, using the one- to-one ratio. If blood component therapy is not available, fresh whole blood would be recommended if it is available where blood component therapy was not available, and then to continue the resuscitation as needed to maintain the target blood pressure or clinical improvement.

And then, lastly, from the traumatic brain-injured casualties, we took out the altered mental status determinant and carried over the weaker absent peripheral pulse, and then if blood pressure monitoring is available, those folks, again, looking at the Brain Trauma Institute guidelines, they recommend at least a blood pressure of 90 or better as their guidelines, and we went along with their recommendation on that.

Slide, please. The only change to the

tactical field care fluid resuscitation was to have the altered mental status in the face of traumatic brain injury, make that reflect the same as in the tactical evacuation care, but we did not address any of the components of the fluid resuscitation strategy in the other subheadings. Slide, please. The proposed change was approved unanimously by the board on August 3, 2010, and then subsequently approved unanimously by the Trauma and Injury Subcommittee of the Defense Health Board on August 3, 2010.

And slide, please. I think that should bring us to the questions.

So, again, Dr. Poland, I open it to discussion before we enter into the --

DR. POLAND: Okay, questions from members of the board?

Dr. Kaplan?

DR. KAPLAN: Kaplan. Is this meant across all services or is this just the Navy and Marines?

CPT TIMBY:: This would be across all

services, sir.

DR. KAPLAN: Thank you.

DR. POLAND: Russ?

DR. LUEPKER: Luepker. A couple of years ago, we had a subcommittee looking at the transfusion of fresh whole blood from service members out in the field. We were unenthusiastic about that. It seems as I look at your fourth from the last slide, that fresh blood is the option without much discussion or debate.

Am I missing something here?

CPT TIMBY:: No, sir. There was actually quite a bit of discussion and debate. Frank, correct me if I'm wrong. I believe it was November of 2009, we had a separate meeting. This was, again, one of our scheduled Committee on Tactical Combat Casualty Care meetings where blood use in theatre was more broadly discussed, and the discussion was rather lengthy.

Frank, if you would expand on that.

DR. BUTLER: Yes, sir. We've tried our best to dissuade our forces from the concept of

doing buddy transfusions on the battlefield because you know what? They're still on the battlefield, and the guy who's not shot next to me now may be shot 30 seconds later. In addition to which the tactical field care environment doesn't really lend itself to the level of attention to the medical procedures at hand that you want to have to do blood transfusions.

So, this recommendation is confined one, to the tactical environment or the tactical evacuation care, where you can have potentially a physician, a nurse, a paramedic supervising care and be only in those circumstances when blood components are not available and that is in accordance with the March 2010 memo on fresh whole blood out of ASD Health Affairs.

CPT TIMBY:: And, Frank, if I can expand on that, it also was in that aspect of the guideline proposal; we fell in line with what was the clinical practice guideline for the CENTCOM AO, Area of Operations. So, again, I didn't just write that as just in case, it was actually in

compliance or in keeping with the current guidelines that were already there in theatre, and that's why it all falls under the heading of an approved command or theatre protocol.

DR. LUEPKER: Let me make sure I understand this. So, the Ultra Fresh Blood Protocol is under the evacuation circumstances and still not recommended in the acute circumstance?

DR. BUTLER: Yes, sir.

DR. LUEPKER: Okay, thank you.

DR. POLAND: Dr. Parkinson?

DR. PARKINSON: Mike Parkinson. Thank you, Captain Timby, and, of course, Frank, for your excellent work here.

I personally come down -- all the hard work has been done -- and endorse the guidelines, but I kind of stand back a minute again and say what can bringing this to the Defense Health Board be of value beyond the guidelines? And the documents that you've presented and the work that has been done back to the board I think has been most valuable, at least to this member, because,

first of all, again, what it shows is whether or not the level of evidence and the recommendation parallels or not that used in internal medicine or preventive services, and it's actually an ACC and AHA, if I've got this correct, it's the flip in terms of the level of evidence and the recommendations that come from those.

But as I go through the whitepaper document here, as a non-surgeon, it begs the question: What can the Defense Health Board bring to the process of an evidence-based maturation for trauma and surgery care? That sounds a little global, and it's not meant to sound negative, but again and again, august bodies of stellar names in the field that are cited with C-level evidence, which is largely we got together, we produced a report, it was based on a case study, and it went forward, it seems to me that there might be some other way of national, international use that the DHB could put a little brain cells to this.

Is there ever the role for an ethically-sound RCT in an area of trauma or war

care or something beyond what we've done? That's just a thought. I do think though that the work is just absolutely superb, but beyond saying absolutely, we agree with every other body that's had expert experience in trauma casualty care and more, and OR theatre, most of the board members, what can we add to the process is what I'm asking?

And this document has been most helpful to me to illuminate a little bit of a framework that would be traditionally used for any other medical intervention from preventive to a therapeutic intervention, whether it's a prescription drug or immunizations? And yet, it you look at whether or not one implant works better than another in non-traumatic situations, the whole field of surgery in general, which is why it's such a topic at CMS and other areas and why it's absolutely cost-wise going through the roof, it doesn't seem to apply to the same level of evidence standards that we traditionally pursue in other areas. Not meant to be negative, just meant to be how can we add a little light so that

a year from now or two or three years from now, we can talk about some methodologies that, perhaps, aren't there yet. Just a thought.

DR. POLAND: Dr. Lewis and then Dr. Shamoo.

DR. LEWIS: Dr. Poland, did you want to discuss the pros and cons of the specific issues or was Captain Timby going to present more material? I know there's a good deal more material.

DR. POLAND: Yes, there's another about third or so of the presentation to go.

DR. LEWIS: Right.

CPT TIMBY:: Yes, the topics that we discussed during the teleconference, we have further information to expand on those topics that we discussed.

DR. LEWIS: I'll wait.

DR. POLAND: You want to wait? Okay. Then maybe we'll proceed on then to the next part of the presentation.

CPT TIMBY:: Slide, please. Okay, these

are supplemental slides. The ones you saw before were the main body of slides that we had forwarded prior to the teleconference, and these are now supplemental slides to address those issues that were raised during the teleconference to help to address that information. Slide, please. The teleconference was conducted on October 21. Dr. Lewis, thank you for your participation. That really helped to kind of bring some of the issues to the forefront that we needed to address. And then additional information was requested out of that.

And if you will, slide, please. Dr. Poland has asked for a copy of the results from the USAISR, that's the U.S. Army Institute of Surgical Research, Fluid Resuscitation Conference, which was just conducted in January of 2010. We'll look at the membership for that conference and the outcome of it in just a second.

And then, also, just in general, the Committee on Tactical Combat Casualty Care membership, who makes up the committee, how do we

go about our decision-making process, which is kind of an interesting thing for those on the board, and then the information distribution as guideline approvals are made or as guideline recommendations are approved, then how do we then distribute out to the branches and implement them into use?

Dr. Lewis had questions more on the basic science side of the house. Using Hextend, is that the right fluid? Offering issues relating to coagulopathy or other agents of equal or similar benefit: Lactated ringers, dextrans, hypertonic saline with dextran, albumin. And, also, we discussed for some length the intravascular dwell time effect of Hextend and the pharmacodynamics of that. And then ending on the not all hetastarches are equivalent and what are the differences, and is there a different product that would be more beneficial? And then, secondly, was then the use of mental status and radial pulse character as indicators of shock in the field.

Slide, please. The committee members, Committee on Tactical Combat Casualty Care, here's kind of a list of the general categories of folks that are on the committee. I won't read those to you. A couple of highlights though. Two command surgeons, U.S. Special Operations commands, there's trauma directors from level one trauma centers. We have actually a member who was on the committee and then was approved for the White House Medical Office, and so, he actually is working up there then.

I'll tell you the real power block and real strength of, I think, the committee comes down lower in the slide. Now, my name seems to have fallen off the bottom of the slide. I apologize for that. No, but these guys down here, these senior enlisted medical advisors and the Army Ranger Command surgeons and really these senior medics, because there's a lot of times where we eggheads on the group oh, yes, I think it'd be a great idea to do X, those guys sit there and shake their heads and say doc, that dog

doesn't hunt, and the Ranger guys, they'll form a voting block and block out anything that just doesn't make sense to them. But, again, they're also very appropriate in coming forward with recommendations, and I would say probably at least 50 if not two-thirds of the change proposals come out of their experience in the field. And so, they are very welcome participants in the committee membership.

The other thing that's very important, none of this, we don't wear any uniforms in the meetings, which is nice in terms of the bag that I have to carry to drag all that stuff with me, but, more importantly, I don't want the number of stripes on somebody's sleeve to make the difference between who has the right idea, and that is very, very firmly adhered to, that anybody on the committee carries the same weight of recommendation as any other.

Slide, please. The committee gets input from all kinds of direction, but listed here are just some of the major ones. Again, published

pre-hospital trauma literature, which Frank is probably the bird dog on hunting down most of that stuff. The Joint Theatre Trauma System, weekly trauma teleconferences is another good source of information where current issues are brought to the forefront. Direct input from our combat medical personnel, again, with the senior medics representing 6, 8, 10 deployments into Iraq and Afghanistan, they've come back with a host of good ideas.

Research facilities, we have really a good amount of information coming in independently from a variety of military and otherwise research facilities, just new technology that may come to the forefront, and then service medical lesson learned centers, again, make up kind of the main part of our information source of issues to be brought to the committee.

Slide, please. How does that information as a guideline get approved, how does that then get disseminated out into the services and then approved? I can tell you firsthand down

at the Camp Lejeune at the Second Marine Expeditionary Force Surgeon's Office, this guy, his chief, bird dogs this probably on a monthly basis just to see has anything changed? So, I would say if there's anything that we do differently in terms of disseminating information, just to make it easier for them to pick out the things that have change, whether that's a red font, whether that's a highlight, whether that's whatever, that it makes it just easier for them to go holy cow, wait a minute, that's a difference, and they incorporate that immediately into their training, and they'll oftentimes come to me, at least in the last couple of months, they'll come to me and say hey, doc, what does this mean? What was the intent behind that? How do we train that? How does this change what we're doing?

But if you look at the Navy letter here from the surgeon general, again, out to the major components, the proposed changes to TCCC guidelines are reviewed by Trauma Injury Subcommittee, Defense Health Board, and Corps

Board of the Defense Health Board, and then once approved, that curriculum changes and then posted on the MHS website, all Navy medicine training sites are then authorized to incorporate the changes as soon as possible. So, there's not another layer of decision-making between the Defense Health Board core decision and then the implementation by the services.

Slide, please. And just by way of showing the Air Force has a similar philosophy in terms of pushing that information forward. I can't speak to the Army.

Frank, do you know? Is there a letter of similarity to that?

DR. BUTLER: The Army is well represented enough on TCCC Committee and with the participation from the Army Institute of Surgical Research that they've typically implemented the changes about three months before the rest of the services.

CPT TIMBY:: And, again, the important point is down here, effective immediately all

changes are then pushed forward or are recommended to be implemented into those current training programs.

Slide, please. This is from the U.S. Army Institute of Surgical Research Fluid Resuscitation conference. This was January 2010, held in Dallas-Fort Worth. Scheduled for publication Journal of Trauma, March 2011. The final draft was submitted to Dr. Poland for his review. Again, just to see the substance of that information that will be published.

Slide, please. These are the members who the report was prepared by and participated in the conference, among others who were much more robust representation.

Slide, please. Excerpts from the conclusions sections is most important, is the restricted use of crystalloids for the resuscitation to prevent fluid overload and particularly Compartment Syndrome, as it may effect the abdomen, lungs, head, et cetera. Early hemorrhage control. Hextend, though it has not

been found to improve survival over and above other agents that were out there, it has also not been found to produce coagulopathy or other significant negative effects. And then, lastly, in combat and at times when cube weight ratios are important, this is found to be the correct solution for its use.

Slide, please. Here, the TCCC guidelines as they are currently published, and as I previously showed, that those guidelines were supported unchanged. Now we then turned around and started changing them. But we did not change them in substance; it was more in clarity of how those guidelines were written.

Slide, please. In terms of Hextend use, to get into the basic sciences issues. Slide, please. Looking at Dr. Holcomb's publication from Journal of Trauma in 2003, and this was at one of the fluid resuscitation conferences, absolutely clear logistic benefits for the military medics to carry the smallest volume and weight of resuscitation fluid consistent with effective

practice.

Hypertonic saline with dextran was not at that time and is not now FDA-approved, so, not available for use. Thus, Hextend represented the next logical choice. If you look at other agents, albumin needs refrigeration, can't carry it forward. If you look at the dextrans, problems with anaphylactic response to that has limited its clinical use.

Slide, please. If you look a study by Mortelmans in the European Journal of Anesthesia in 1995, looking at the dwell time of Hextend or actually hetastarches, 8 healthy volunteers, limited fluid intake, limited food intake were then bled 500 CCs of blood volume and replaced 1-to-1 volume with 6 percent hetastarch, and with that, looked at then the systolic blood pressures, intravascular dwell time, et cetera, and, again, the intravascular volume was found to be isovolemic for an 8-hour period. In the current war effort, the evacuation times certainly fall easily -- well, I wouldn't say "easily." We fall

within that eight-hour guideline at this time. We tried to adhere to the Golden Hour Philosophy, more of a stop the hemorrhage philosophy than the Golden Hour Philosophy. We are probably having the vast majority, I would argue. I don't have the data to say, but we have a good proportion of our folks are back in surgical hands within a 90-minute if not a 2-hour period.

Slide, please. If you look at the Marino Handbook published in 2007, the ICU Book, the hetastarches equivalent, this is his statement, "5 percent albumin as a plasma expander." Major difference between the two fluids, cost. The hetastarch is cheaper, and then the risk of altered hemostatis, which is greater in the hetastarches.

Slide, please. If you look at a recent publication, Journal on Cardiothoracic Vascular Anesthesia 2010, Murphy and Greenberg stated the FDA has stated that Hespan use is not recommended during cardiopulmonary bypass because of an increased risk of coagulation, abnormalities, and

bleeding, and it's similar FDA warnings have not been extended to the administration of Hextend or Voluven, which is a smaller molecular weight-averaged product this is FDA- approved, at least in those folks with cardiac surgical patients.

Slide, please. If you look at the graphs to the right, these are different hetastarch products. Again, if it is a 6 percent hetastarch, it is isovolemic to plasma. The other numbers here, the 450 versus Hextend, which is a 670, is the average molecular weight of the product, but, again, as the term that they use, it's a polydiverse, meaning this is just the average molecular weight of the product. There are molecules within each solution that are higher or lower, and it's kind of a bell curve distribution. If you look at the molecular weight as opposed to what is the molar substitution, each glucose molecule has opportunities for hydroxyethyl esteration and blah, blah, a lot of pharmaco, pharmacology, biochemical type stuff,

but the bottom line, this tells you the number of molecules for every 10 glucose, how many of them are actually substituted. The higher the substitution, the less likely it is to be metabolized by plasma amylase, and, thus, its dwell time is expected to be longer. Hextend has a alpha half-life, alpha meaning immediate elimination from the plasma of about 6.3 hours. So, again, that kind of falls into about the timeline of the dwell time that we saw with that.

Now, when you talk about the plasma half-life, you have to be a little bit careful because the hetastarches, again, because this is an average, if you go down to the smaller molecular weight average products, some of those will fall below the 45 to 60 kilodalton size that are rapidly cleared by the kidney. Those that are larger remain within the circulation, but, again, if you have a smaller molecular weight at the beginning on average, then more of the product will be eliminated more quickly, and then if you have a lesser molar substation, that also then

portends a faster metabolic rate. And so, again, it would be more quickly cleared from the circulation.

So, again, agree with Dr. Lewis' assertion that not all hetastarches are the same. They are not. They are actually 10 percent solutions which are hyperosmotic. There are 3 percent solutions that are hypotonic, relatively speaking. The ones usually commercially available in use in the U.S. are the 6 percent hetastarches.

When you go to Murphy's Journal of Cardiothoracic and Vascular Anesthesia, although dextrans may attenuate the inflammatory response and have other features that make them good for use, in pulmonary bypass, there are rarely used clinically because of the risk of life-threatening anaphylactic reactions. And then if you look at the colloid effect of the third generation hetastarches, which are the ones that are the smaller molecular weight and lower molar substitutions, they are as a colloid effect equivalent to Hextend, but the elimination

half-life tissue deposition and side effects, coagulopathic effect, those features of the products are different. But, notably, the volumes of hetastarches required were not significantly different in cardiac surgery, in orthopedic surgery, and clinical outcomes in all groups were comparable. And that's a Westphal anesthesiology article from 2009.

Slide, please. The Ryder Study, published in the Journal of American College of Surgeons 2010 looked at 1,714 trauma patients arriving at the Ryder Trauma Center in Miami. They were resuscitated with either standard of care or standard of care with Hextend. In the non- randomized format that they used, so, again, it's kind of a level C data, that was largely because of Florida law prohibiting pre-hospital use of informed consent, blah, blah, so, they couldn't do it until they reached the hospital despite that, and either members or any of the patients that were treated with the hetastarch Hextend in this particular case was associated

with a reduced initial mortality and no obvious coagulopathies, and they had folks who received well above the 1,000 CCs that we recommend.

Slide, please. This comes out of the excerpts of the point paper that I had submitted to the board prior to the meeting, again, looking at the level of evidence supporting and not supporting the use of Hextend. Again, if you look at colloids better than crystalloids, again, the literature is pretty much un-supporting in terms of saying colloids are better than crystalloids. However, three major fluid resuscitation conferences, one by the Institute of Medicine, 1999, where they actually recommended the use of 7.5 percent saline. However, most of the supporting literature that they used in that was actually 7.5 percent saline with dextran. Nonetheless, their recommendation was actually for use of the hypertonic saline. The Combat Fluid Resuscitation Conference of 2001, conference recommended by a fairly narrow margin Hextend or hetastarches for the use, and then the

pre-hospital fluid conference from Dallas, 2010, also favored Hextend largely because there is no literature to support anything being of greater benefit. If you look at the Cochran Database Systematic Review 2008, again supports the use of hetastarch as the fluid of choice.

The NIH News, this referenced the two large, randomized, multicenter, yadda, yadda, all the good stuff that you want in research studies. Looking at 7.5 percent saline in trauma patients and then a second study looking at the traumatic brain-injured casualties, both of those studies were stopped prematurely about halfway into the study design because of failure to demonstrate efficacy. Again, you can poke it in the eye about the decision to stop a study midstream, but the bottom line that the end term analysis, there was no benefit of the hypertonic saline versus conventional therapy. And so, again, that is probably the best level B data that we have to say that not so much that Hextend is the right choice, but that hypertonic saline is not the right

choice. So, again, I use that as supporting evidence. And then a variety of papers published, again, supporting expert opinion across the board stating that the hetastarches as the product of choice.

And is Hextend the best? Again, some support, some don't support. Again, I don't think that there's really great evidence to support that absolutely it is the agent of choice, but there's certainly not evidence of anything else pushing it off the table either. And then, again, lots of studies down here below. I use just a handful of them that I selected to show the safety and efficacy of the agent of choice.

Slide, please. Indicators of shock in the field slide, please.

If you look at the electronic blood pressure monitoring, our combat medics do not currently carry any kind of electronic device or even just a manual device into the field, and when I ask them if you had that option available to you, would you want it? And they all do the east

west. No, I don't want it. Reliance on electronic blood pressure monitoring is, therefore, not part of the care under fire or the tactical field care. Slide, please. But it is actually one of the recommended change proposals for using that as a measure within the tactical evacuation phase. And, again, we advocate that, using the target 80 to 90 mmHg and those with uncontrolled hemorrhage, and 90 or better in those with Traumatic Brain Injury and Shock.

Slide, please. If you look McManus' paper from 2005 in pre-hospital emergency care, looking at mental status and radial pulse characters, the analysis showed that mortality was 29 percent in the patients with a weak radial pulse compared with the mortality of 3 percent in patients with a normal radial pulse character.

Slide, please. This is further supported by a study by Holcomb, et al., and in their cohort, they looked at mental status and radial pulse characters, indicators of shock in the field and looked at the multivariate addition

of certain procedures to say how much more does having blood pressure, systolic blood pressure, mental status, et cetera, how does that support the decision to do a lifesaving intervention? And, again, I hate to quote numbers because I can never remember them, but they're in the high 80s. I believe it was 85 the addition of systolic blood pressure measurement over radial pulse character or presence. Took it from 85 to 88 percent in terms of predicting whether the member would receive a lifesaving intervention, and when you took the verbal portion of the Glasgow Coma Scale and added it to the pulse character or presence, it went into the low 90s to say that that was, again, a supporting piece of evidence.

So, if you look at radial pulse character, 85 to percent -- I forget what the number was -- were able to make the decision based on pulse character and presence. They got an additional 3 percent by being able to say that the guy's systolic blood pressure was 90, and they got into the low 90s by being able to say that the

guy's mental status was pretty good, was acceptable or not acceptable. So, again, looking at it, radial pulse and character offering the greatest selection or ability to differentiate those who needed a lifesaving intervention or not, and then the addition of systolic blood pressure and mental status then supported the greatest additional outcome measures.

Slide, please. So, if you look at the eastern -- Frank, help me with the east. What does that stand for?

DR. BUTLER: (inaudible)

CPT TIMBY:: Thank you. If you look at their guidelines, fluid should be withheld in the pre-hospital setting in patients who are alert and have the palpable radial pulse. So, within their own set of guidelines, they use palpable radial pulse. So, again, accepted by a large, pre-hospital care organization.

Slide. Okay. I think that brings us to the end.

DR. POLAND: Okay. Opportunity for the

board members to make comments.

Dr. Lewis?

DR. LEWIS: Let me comment, if I can, about three things about this. First, I'd like to address is the issue of resuscitation and Hextend and the value of that. The physiology of fluid resuscitation is quite well-defined. The science underpinning it is quite solid, and the way in which fluids exchange across body water compartments is quite well-defined. There's an intracellular compartment and interstitial compartment and intravascular compartment. The interstitial is about three times as large as the plasma volume. So, when you give a salt solution, which is isotonic with that, it redistributes into the interstitial space rapidly, and, therefore, the retained volume is only about 25 percent, but that's permanently retained.

When you're going to analyze the effect of any resuscitant fluid, there are only two characteristics that make any difference in that. One is the oncotic pressure, which is the pressure

due to the large molecules. The other is the osmotic pressure. That due to small molecules. Small molecules cause fluid transfer across the intracellular membrane. Large molecules cause fluid transfer into the vascular space across the capillary endothelial membrane.

When you're talking about Hextend, you're talking about oncotic pressure, and the only tendency to pull fluid into the circulation or to retain fluid is due to its oncotic pressure, and there's a significant error that's propagated through much of the information here. It's most apparent in the quotation from Marino that Captain Timby gave. It says, "Overall, hetastarch is equivalent to 5 percent albumin as a plasma volume expander." That's a totally false statement. Okay, the oncotic pressure of any large molecule solution is equal to the physical weight which is present divided by the molecular weight, and what's absent from all these discussions is any discussion of the molecular weight, which is highly variably among the solutions. Hextend has

a molecular weight average of 660,000. Albumin is 64,000. So, Hextend has one-tenth the oncotic pressure of albumin on an equivalent weight basis. Therefore, saying that it's "equivalent to 5 percent albumin" is untrue. It's equivalent to one-tenth of 5 percent albumin. And that's what's missing from the discussions.

Giving 600,000 molecular weight Hextend is basically equivalent to giving saline. The only difference between Hextend and Hespan is that one's an imbalanced salt solution and the other's a saline solution. The molecular weight of Hespan is averaged about 330,000. Of Hextend, it's about 660,000. So, Hextend has one half the oncotic pressure of Hespan, and Hextend has one-tenth the oncotic pressure of Dextran 70, for example, which is quite close to albumin.

So, what's missing from the discussions is any concern about the molecular weight of the large molecules which, in fact, makes all the difference in oncotic pressure. So, the studies, one has to be very, very careful when citing these

studies. Fluid balance studies are very hard to do.

As an example, I would cite for you in the 1980s, there were four prospective randomized studies done of crystalloid versus colloid in resuscitation. One study concluded that colloid was clearly better. One study concluded that crystalloid was clearly better. And two studies concluded that it made no difference. They were all class A studies. So, one has to have considerable skepticism about studies because they're very hard to do. There is no method for instantaneously measuring the volume of intracellular fluid. They are all indicator dilution techniques, they take time, and they are significant inaccuracies.

So, as Captain Timby has shown, virtually all of the studies that are cited are class C studies. Most of them suffer from lack of randomization and lack of clear endpoints. So, one has to be quite skeptical about them, and when the science of this is quite well-defined, one

should consider it. So, the issue with Hextend is that it's a relatively ineffective resuscitant, basically the same as saline. When one gives 1,000 CCs of Hextend, it's like giving 900 CCs of saline plus 100 CCs of plasma equivalent, and that's going to have very little resuscitative effect. So, the issue here is that the use of Hextend is probably not harmful, but it's probably not very helpful, and since it costs 24 times as much as saline, then it's probably not warranted to use it. So, I would say that's my comments about resuscitation.

The concern about cube weight is obviously a huge area for the medics. If one really wanted to do anything about that, the only solution currently available that's safe is hypotonic saline dextran. Two-hundred-fifty CCs of 7.5 percent saline gives you an intravascular volume equivalent to 2 liters, and so, that's an 8-to-1 ratio. So, in terms of cube weight effects, one gets the same effect for one-eighth of the weight, and that would be, in fact, a very

positive change. But there's no other solution around, which would have any advantage, and Hextend has no cube weight advantage over saline if you recognize that it has minimal oncotic effects.

My second comment is in regard to the recognition of shock. Recognition of shock on clinical grounds is extraordinarily difficult, even in the hospital setting, and mental status changes only occur at the most extreme levels, systolic pressures in the 40 to 50 range before patients sustain cardiac arrest. So, they are not erroneous; they're just quite late, and so, one has to be very careful about considering them as a useful indicator because I think it would be difficult to assess their accuracy. Radial pulse is most accurate if one has a blood pressure cuff and can inflate the cuff until the pulse disappears.

That's not what's present here, and what I've suggested is that the military should consider the fact that there are ambulatory blood

pressure monitors today of using ultrasound technology that are about the size of a pack of cigarettes, run on batteries, weight about six ounces. They are routinely used for ambulatory blood pressure monitoring. They're extremely accurate, and they might not be appropriate for the frontline field application, but they certainly would be applicable for the evacuation chain at some point when there's a little more stability, and basically what's needed is an accurate monitor of blood pressure, and the only way to do that is some sort of effective blood pressure measurement. All of these other indicators are quite erroneous. It's been shown that paramedic measurement of blood pressure is a little better than a rounded number in the field, for example.

So, one has to recognize that under conditions of the field, noise, movement, agitation, a whole bunch of things, it's a very difficult number to obtain accurately, and I really congratulate Captain Timby and all the

people who have done the work on hypotensive resuscitation over the last 15 years. That is excellent work, and certainly is appropriate as an indicator. So, my quibbles with this are about purely the indicators for shock, not at all about the fundamental recommendations.

Lastly, it's really a quibble, but the blood pressure of 70 to 80 is probably higher than needed. Blood pressures of 60 to 70 would probably be perfectly adequate as a hypotensive level, as was shown in some of the earlier work dating from World War I, and that's probably appropriate.

So, my overall comments are Hextend is not harmful, but it's quite expensive, and it does nothing more than saline basically, and the indicators of the level of shock are highly difficult to ascertain, and I think the military should consider an evaluation of the ambulatory blood pressure monitors for applications somewhere in the chain because they're small, light, and would not be a major addition to what's already

being carried. Thank you.

CPT TIMBY:: If I could address the blood pressure monitoring for the ambulatory blood pressure, again, those are perhaps the right answer to the wrong question issue. In the ambulatory blood pressure monitoring, we are largely as internists, cardiothoracic folks looking at hypertensive management and what is the range of the blood pressures that those members may be experiencing? Again, usually, a fairly controlled environment. You're not far forward; you're not in the back of an ambulance. You're certainly not in the back of a helicopter. So, without seeing specific literature showing the sensitivity specificity, all the good stuff that we like to see to make decisions on something's applicability, I'd like to see it in the environment by which we will be using that.

In the fully-equipped evacuation platform of an evacuation, and, again, we use terms Casevac and Medevac, if you have a medically-regulated evacuation platform, i.e.,

medical personnel on the back of the helicopter, that is commonly referred to, and, again, services different, as a Medevac. Regardless of the term, that's why we've gone to tactical evacuation to get away from that. We're looking at point of injury back to first surgical opportunity as the phase of care we're looking for. I don't care what you call it.

Anyway, in those platforms, right now in Afghanistan, a large part of those are happening by helicopter. In the back of those helicopters are ProPACs, which are basically a very sturdy, very rugged, very aero medical tested -- again, I go to my Air Force brethren to say those things are tested and tested, and tested in the population that we're looking at, causalities. And just in the teleconference, a late entry was John Gandy, who was the Air Force Special Operations command surgeon for a number of years, and, thus, got his membership on our committee. John's comment was that they had tried some of those small units in the back of the helicopters

really just in exercise play and whatnot and got blood pressures that were just all over the page.

And, again, a random number generator probably would have given you as much accuracy as the monitors themselves. I say that tongue in cheek. What he actually did say is the blood pressures varied by 10s and 20s whereas the ProPAC gave a very consistent, solid, little variance. So, again, what their determination from that was the equipment they had worked, gave them reliable information, and they did not find that the other agents were helpful in that setting. Again, not published information, but personal communication from the Air Force Special Operations Command surgeon in their field trials of just, hey, do these things work?

So, again, I would argue that in a tactical evacuation phase that we have the equipment that does the right thing, and I think we have the right measures. And, again, I appreciate your comments. I think the discussion at the committee level, what was the right number?

Seventy to eighty, I think, was my initial proposal. We argued it back and forth. It ended up at 80 to 90. Again, I don't have a strong --

DR. POLAND: I think those latter two issues on should it be 70 or 80 and what kind of blood pressure -- I think are much more minor issues that aren't going to be resolved by this board. I think the more substantial one is around the fluid resuscitation.

So, other comments? Dr. Shamoo?

DR. SHAMOO: Yes. As you know, we've talked some of this over a year ago.

DR. POLAND: Right.

DR. SHAMOO: And I want to augment what Dr. Parkinson said, and it's really addressed by Dr. Lewis' comments, and that is you could see there are too many variables, and the evidence we're depending on, they're at best moderate and may be to the range of poor, moderate to poor. I agree with you this is the status of medicine.

In the late '40s, the only way they measure radiation effect, they put a rabbit in a

nuclear reactor and see if they die. I mean, that was how you start science, unfortunately. You can't do a very sophisticated work when you start at the very, very beginning. We are not at that stage here. But we can recommend just what Mike said and what we said a year ago, and, obviously, nobody has done anything about it, is to design a research protocol concomitant with their use of the current status of knowledge. The design will be difficult, technically very difficult in a combat area, and ethically challenging, but, nevertheless, there should be an attempt to design and carry out such a research. Otherwise, we're going to be back two or three years from now at the same point with moderate to poor quality evidence.

DR. POLAND: Sorry, I'm not sure of your name.

DR. CHAMPION: My name is Howard Champion. I just would like --

MS. BADER: Dr. Champion?

DR. POLAND: Can you come to the

microphone?

MS. BADER: Can you please come to the mike? That helps our recorder. Thank you very much.

DR. CHAMPION: Better? I would like to insert a couple of comments relative to the last speaker's suggestion that we carry out these studies in the combat setting or even in the civilian setting. There have been probably 20, 25 attempts in the past two decades to marshal studies that will address the issues of fluid resuscitation in post traumatic shock, and they have all failed for one reason or other. They're extraordinarily difficult to undertake because of the case definition of patients, the confusion with other injuries, head injury in particular. The frequency is low. They account for about 3 to 4 percent of patients admitted to the average trauma center. That means you have to have multiple centers on common protocols of therapy in the middle of a Saturday night implementing these things, and it's not for want of trying that we

have failed miserably to marshal sufficient evidence to get a study comparing resuscitation A versus resuscitation B. I don't think there's any one of us in this field who wouldn't like to be recommending alternatives such as HSD, which is not approved by the FDA, despite 20 years of attempts to do so, or freeze-dried plasma, which is used in European countries and NATO forces working alongside American forces, are using it in Afghanistan today. So, we're behind the curve, but putting the solution down to getting class A evidence for this data is a little bit somewhat distracted from reality. We have really, really tried.

I was the data control monitor for the Factor 7 Studies globally and read into all of the difficulties of doing this at multiple sites, let alone multiple countries. So, we're putting forward today the best we can, and we are continuing to try hard. Dallas Hack, who's the commander of Combat Casualty Care Research at MRMC, is working with Colonel Holcomb to stand up

a multi-center trial in the United States as we speak. It will hopefully get 20 centers working together in a cohesive fashion to begin to develop methodologies that could begin to answer these problems. But it's not here today, and it's not going to be here in three years.

DR. SHAMOO: I agree with you fully, and, as a matter of fact, for five years, I was the consultant to ONR's clinical trial on blood substitute, and after five years of trying, getting preliminary data, you name it, and even doing some of the work in South Africa, and the FDA stopped us. So, I am very aware of the difficulties, but I don't think we should stop trying.

DR. POLAND: I don't think the board will have a problem with adding some statement about encouraging and supporting randomized clinical trials, but other than that statement, it's outside our sphere of influence. Let's leave that thread of discussion and focus on what is before us.

Dr. Jenkins?

DR. JENKINS: Don Jenkins -- can you hear that? -- from Mayo Clinic, Rochester. Frank, correct me if I'm wrong, but we do have some evidence, low-level evidence, but practical evidence from the 75th Ranger Regiment. About 3,500 troops over a 10-year period, this is put in a publication, that's being reviewed for publication right now, about 430 casualties in that 10-year period of time of continuous combat, 32 deaths. Each of the deaths reviewed, none of them preventable.

They have been following this exact protocol throughout that period of time. Trained on it using Hextend, using all the tactical combat casualty cure techniques that you've heard about here today, and a case fatality rate that's less than half that of the conventional forces. So they've had this in place for 10 years whereas conventional forces really have just started to adopt this in the past 2 years.

So I would say -- I would submit that in

terms of available evidence is Hextend harmful, I could tell you that Russ Cotwall and Master Sergeant Harold Montgomery would tell you that, A, it's not harmful; B, it's their fluid of choice and they're not going to take saline into the battle space with them. They don't own a blood pressure monitor. It can't be done under the circumstances we're talking about where people are shooting at them. And every bit that they carry on their back does make a difference to them.

So I would submit that the evidence is there. And I think those are -- while I rounded those numbers off, that's pretty accurate. You're talking about a case fatality rate that's less than 4, which is less than half of what was reported at the beginning of the war in terms of a case fatality rate of 8 to 10, which is half that in Vietnam. So I would submit that there is some evidence that's out there.

And to the comment about, you know, what can this group do, I would submit to you that the evidence exists in the Joint Theater Trauma

Registry within the Joint Theater Trauma System, endorsing research of the available evidence. Facilitating that research I think would be something that this group could surely do, to look at the actual hands-on experience from the battlefield.

DR. POLAND: Dr. Butler.

DR. BUTLER: Yes, just to follow up on Dr. Jenkins' comments, didn't want to quote data that has not yet been published, but if the New England Journal accepts it, it will document the lowest rate of preventable deaths in combat ever recorded in modern warfare. Now, how much of that was Hextend versus how much of that was controlling the hemorrhage in the first place, I'll leave it for you to decide when you read the article. But the difficulty that we have had to overcome was the 15-year-ago large volume, just flood them with lactaided ringers. And I will tell you, at the January ISR Fluid Resuscitation Conference 15 years later, there was not one voice -- not one voice -- raised in support of that

previous strategy.

So I don't think we have the final answer, but I think we have clearly moved beyond large volume crystalloids.

DR. POLAND: Dr. Walker.

DR. WALKER: I was most impressed by the potential for the advantages of lyophilized plasma. And I want to know how can the Defense Health Board facilitate getting FDA approval for this product? I think it would offer lots of advantages. It'd be, I mean, a whole order of magnitude step forward over what we're doing now.

DR. POLAND: I don't know. Does anybody know the answer to that question? Generally you can't have the FDA do anything. (Laughter)

DR. BUTLER: So the number one research priority recommended by the ISR Fluid Resuscitation Conference was exactly what Dr. Walker said, lyophilized plasma. The U.S. Special Operations Command's command surgeon went to Dr. Rice and said, hey, our coalition partners are fielding freeze-dried plasma, using it on the

battlefield. We need to be able to do this, too. And is still squarely -- well, I guess it's not in Dr. Rice's lap anymore. It's now squarely in Dr. Taylor's lap.

DR. POLAND: Sounds like people are pursuing it.

DR. BUTLER: So I think that may be coming to the Defense Health Board.

DR. POLAND: Other comments?

CPT TIMBY:: To add to that, my understanding is casualties that -- actually these are U.S. casualties who are evacuated to Bagram or German facilities or other NATO partners. Our service members are receiving lyophilized plasma. So, again, depending on if it's a MERC team that goes out to evacuate or if it's somebody else makes the difference as to whether you're going to get a blood product, lyophilized plasma, a physician on the back of the bird versus not. And that adds credence.

DR. POLAND: Okay. I think the point that we're at is we have the best available

evidence and we have a preponderance of that evidence. We have the imprimatur of multiple professional societies that have looked at these data and, with the limitations stated, have come up with the recommendations that you have before them. So I'd like to entertain a motion to approve the guidelines.

DR. MASON: So moved.

DR. POLAND: And a second?

DR. PARISI: Second.

DR. POLAND: Any other discussion? If not, if we could have those that approve them raise your hand. Any against? Any abstain? Okay, the motion passes.

Dr. Butler, Captain Timby, thank you very much.

CPT TIMBY:: And thank you to the board.

DR. POLAND: We are ahead of schedule, which is a good place to be. What we're going to do is take a break. How long is the break?

MS. BADER: We'll take approximately a one-half hour break. If we can reconvene at

11:10.

DR. POLAND: Okay, long break. All right, 11:10 it is. And then Dr. Halperin, I think, is going to be up to bat. Thank you.

(Recess)

MS. BADER: Please take you seats.

DR. POLAND: Okay, in the interest of starting on time, we're going to start. Given that we are going to stay on time, it will leave a little extra time at the end of the day for PT before dinner. Several of you were going to recommend that strongly. You know I'm teasing you because I love you.

All right. Our next speaker this morning is Dr. James Kelly. He's a neurologist and renowned expert on concussion treatment. He serves as the director of the National Intrepid Center of Excellence. His past positions have included assistant dean for graduate medical education at the University of Colorado School of Medicine, director of the Brain Injury Program at the Rehab Institute of Chicago, and neurologic

consultant for the Chicago Bears of the NFL. Dr. Kelly is consulted frequently by professional, elite, amateur, and youth athletes who have sustained concussions. In addition, he is a fellow of the American Academy of Neurology and diplomat of the American Board of Psychiatry and Neurology, past president of the Colorado Society of Clinical Neurologists, and a consulting neurologist to the Defense and Veterans' Brain Injury Center, a component center of the Defense Centers for Excellence.

Dr. Kelly is going to provide an information brief on the National Intrepid Center of Excellence. His slides are under Tab 3 of your meeting.

Dr. Kelly, welcome.

DR. KELLY: It's a pleasure to be here and an honor, and, Dr. Poland, the one thing that I think wasn't mentioned that perhaps is most important for this group is that I served on this board briefly as the first chairman of the TBI External Advisory Subcommittee, and it was truly

an honor to do so. In fact, the very first day that that committee met was the day that General Loree Sutton and I met at the end of the day and she inquired as to whether I might be interested in such as the dog as the one I hold right now. So, it was a springboard and a wonderful opportunity for me to move in that direction.

So, what I'll do is try to stick with my 45-minute time span. I understand there's a little flexibility in that. I would like to engage the group in questions, and I don't know the format that you prefer. Should we take questions as we go or we should we wait until the end of the discussion?

DR. POLAND: We don't really have a preference. Do you have one?

DR. KELLY: I don't.

DR. POLAND: Generally speaking, why don't we go through your presentation and then ask for questions? Oftentimes, they get answered as we go through.

DR. KELLY: Very good. The Intrepid

Fallen Heroes Fund is an organization which began in 1982 by Zachary and Elizabeth Fisher, both of whom have passed away, and it actually resides on the aircraft carrier the Intrepid that Zachary salvaged from the scrap heap essentially and turned into the museum that perhaps you know about in New York on the Hudson. They also started the Fisher House Foundation, 50-some houses I believe it is now that exist nationwide. One is in Europe. And their fundraising efforts under their nephew, Arnold Fisher, have led to additional opportunities for medical facilities to be created for our military service members, and the bottom picture here, you see is the Center for the Intrepid. Everything, of course, in name is connected to the aircraft carrier itself which opened at Brooke Army Medical Center in 2007, and it's primarily for amputation and functional limb loss care, a true wonderful world-class institution of its own.

The NICoE was officially dedicated and proffered to the DoD in a ribbon-cutting ceremony

just this past June 24. The building is a $65 million gift of the American people by donations to the Intrepid Fallen Heroes Fund, and I'll go through the details of what the building has in it and what the program is that we're building to run it.

But here, I'm sorry it doesn't project better, but there's a lovely gold leaf impressed inscription on Italian marble in the front entryway of the building which reads "To America's military heroes in recognition of your patriotism, courage, and sacrifice, a place to heal the invisible wounds of war," and this is from the American people and the Intrepid Fallen Heroes Fund. So, this dedication appears on the wall right as you enter the building and I think really does tell the story as to what this is about.

The NICoE, the acronym for the National Intrepid Center of Excellence, covers about three acres on the National Naval Medical Center Campus in Bethesda. It's a 72,000 square foot, 2-story building. We ultimately anticipate about 111

personnel in order to serve its multiple missions. And the big-ticket items, if you will, in the building that are truly the most advanced technology that we have are the 3-Tesla MRI Scanner, which I'll go into some more detail about, which will offer functional as well as anatomical imaging. The positron emission tomography scan, the PET Scan, PET CT Scan, magnetoencephalography, which is a magnetic version, if you will, of EEG, looking much more deep into the brain's anatomy, transcranial Doppler ultrasound for blood flow studies, fluoroscopy and conventional X-ray radiography for shrapnel and swallowing studies and so forth.

And then the Computer-Assisted Rehabilitation Environment System, the CAREN, of which there are seven in existence in the world, and five of those are owned by the United States Department of Defense. It's a very sophisticated balanced platform and treadmill combination inside a large virtual reality screen in which individuals then can move about and be tested in a

safe environment, and we can actually assess them as well as provide for specific therapeutic interventions.

The vision of the NICoE is to be an instrument of hope, of healing, of discovery, and learning. And the mission, to be the leader in advancing world-class psychological health and traumatic brain injury treatment research and education.

This actually comes out of the National Defense Authorization Act of 2008, written in 2007, of course, at which time the Defense Department's task by the Congress was to build a center of excellence around psychological health and one around traumatic brain injury. Those became melded, if you will, under the umbrella of the Defense Centers of Excellence when General Sutton came onboard, and at that same time, Arnold Fisher raised his hand and said I'll build it, I'll build you the center. And so, as a builder, being very familiar with military structure and the kinds of things that had already gone into the

Center for the Intrepid down in San Antonio, he decided then with the leadership in the DoD to find the proper location, which ended up being Bethesda, and then pulled together individuals, as I'll show you, meeting many, many times over the last two-and-a-half years in order to build the center as we have it currently.

The key principles of this NICoE are to be a model of interdisciplinary, diagnostic, and treatment planning in a very family-focused, collaborative environment promoting physical, psychological, and spiritual healing. It will be a research hub to leverage that unique patient base. The most current, technical, and clinical resources in order to initiate innovative pilot studies designed to advance medical science in traumatic brain injury and psychological health conditions. It will also serve as an education and training venue for the dissemination of next generation's standards of care and resilience to providers, as well as service members and families, and as an innovative platform committed

to long-term follow-up and family contact.

One of the things that Arnold Fisher will push in virtually every engagement we have with him is I want a string attached to that service member so that you can tug on it down the road a year or two years and say how are you? Did anything that we just did at the NICoE matter? Did it change things? If not, can we adjust fire and help in some other way? Are there services you need in addition to what we're offering and so forth? So, that long-term follow-up is something that we have a very robust system including computer database and telecommunication systems built into the structure of the building for that purpose.

So, in terms of the flow across time here, in the fall of 2007, the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, DCoE was created. NICoE was actually conceived at the very same time to be the hub. Initially, it was thought to be the headquarters for the DCoE, and then that morphed

into various other kinds of opportunities with time, and DCoE being then the umbrella over NICoE and the other five centers of excellence within DCoE.

The NICoE was proffered as a building to DoD by the Intrepid Fallen Heroes Fund in 2007, and later that same month, General Sutton convened the very first working group in order to determine what the building had to have in it, what kinds of things it was going to do, how it could serve as an institute if you will, much like the NIH model for the combination of advanced clinical care plus research and education.

In January of 2008 through December of 2009, the initial concept of operations was created by that group with input from academic centers around the country, as well as the military leadership, and a market analysis of the clinical and research requirements, including what needed to be in the building technically was all decided. I was hired in February of last year 2009, which was the endpoint of my engagement

directly on this board. And then in spring of 2009 to summer of this year, a variety of meetings and engagements have occurred leading to the ultimate programmatic design and preparation for the initial operating capability, which we are in currently.

The dedication ceremony, the ribbon-cutting happened on June 24, as I mentioned. And then there was an alignment shift from TMA Health Affairs, NICoE was moved programmatically under Navy, being that we're on the Navy Hospital Campus. Naval Support Activities Bethesda is ultimately responsible for the maintenance, upkeep, and so forth of the building. Programmatically, at least to stand up the building, and the program, it made sense to the military leadership to move us, and that was officially done on August 10 of this year. And then, as planned, according to the concept of operations and the initial planning session, October, just last month, we initiated the clinical care with our first cohort of patients

coming through the building, and we are now beginning our third cohort of patients last week and this week.

The org chart looks like this. The dark blue are the personnel that are uniform military. In fact, just recently joining is Rear Admiral Select Naval Captain Tom Beaman who's in the back row over here. Tom, if you want to raise your hand. Thank you. So that if anybody wants to raise Captain Beaman in discussions, he's now in my chain of command within NNMC; and as deputy director and chief of medical operations, Dr. Tom DeGrabga, a Navy captain; Mike Hendee as chief of staff; and then we have deputy directors across this horizontal row here. And all are in place except for our research deputy director at the present time. We have to stand up the clinical operations first and foremost, and then as the organization matures, the research piece will come along.

As you can see, the breakout of the staff numbers, the largest number are 38 within

the clinical operations directorate. We ultimately anticipate 12 unstaffed, uniformed service members, about 90 civilian, and 9 contract personnel.

This is for us to see 20 patients and their family members on any given day in the building once we are up to full operating capabilities. The ongoing research protocols require the usual run through of IRB approval and so forth, and I'll show you that we already have two of those underway. And then training and education will occur for service members, families, and their providers, and I'll go into a little more detail about that.

The main mission, we are a clinical operation on that Navy Hospital Campus to offer specialized, interdisciplinary diagnostic evaluations of complex TBI and psychological health conditions. So, we're talking about combined concussion or relatively mild in the spectrum of traumatic brain injury, mild TBI, and the psychological health problems such as

Post-Traumatic Stress in the same individual.

This is to be provided to the patient and family in a holistic clinical care environment. So, we're asking that family members join the service member at the NICoE. There's also a dedicated Fisher House that has just now become available just 200 yards away. There are three brand-new Fisher Houses being built on that campus, and the first one coming online is the one dedicated to the NICoE.

We will produce a comprehensive, individualized treatment plan. The entire approach is to identify that service member's problems and how that reverberates within that person's family. This is not a milieu treatment program where we bring in all 20 at one time and have them go through the same program together. They come one or two, maybe three when we're fully operational on any given day, and one or two or three will be discharged on a rotating basis as we go. We will be producing an individualized treatment plan during that span of time with the

detailed diagnostic workup that we do, and exporting the treatment plan with that service member back to where they came from or to yet a third location if, in fact, their needs dictate such a decision.

We will measure the outcomes internally and with the collaboration of the receding centers, wherever they end up as to the therapeutic interventions and the treatment plan as to whether it was successful or not.

All of this has been orchestrated by a series of small working groups comprised of expert panels both within military ranks and in the civilian sector as volunteers that have created recommendations specifically about the clinical evaluation process and putting together this treatment plan.

A lot of this really as we stood up the organization required that we actually look outside and with DCoE's help in particular, looked at existing clinical practice guidelines and then creating our own standard operating procedures,

borrowing oftentimes from Walter Reed and Bethesda's National Naval Medical Center in so doing, and actually just modifying them to our particular needs.

We had to also learn what the personnel requirements would be for those various missions and the equipment requirements, and then also what follow-up metrics made sense to use, and we've been very engaged in a national project called Common Data Elements, which engages NIH and other federal partners in determining what traumatic brain injury and psychological health measures should be on a menu, if you will, so that nationwide, we all can communicate in terms of outcome measures along the same lines.

So, the patient that will be coming to us is an active-duty service member with traumatic brain injury complicated by some type of impairing psychological condition who is not responding to the available, more conventional therapies in the military health system wherever they are.

So, that individual, again, will be

active-duty, they have mild to moderate traumatic brain injury at least at the very beginning. We are looking for individuals who have served in our current conflicts, OEF, OIF, OND, as Iraq is now called, and that they have persistent symptoms. So, this isn't somebody that's just recently returned. We want them to have engaged in the system that they're in, wherever that military health system may be, and then if in fact there is not success, then those individuals with complex or complicated problems will be sent to us.

They must have no active or untreated substance abuse disorder. So, we're not an in-patient facility. We won't be doing detox and so forth. And they have to be able to essentially function in a Fisher House setting and come for outpatient care five days a week, maintain their own day-to-day routines in terms of food and transportation and so forth, not be a danger to them self or others, and not be requiring the kind of nursing care that would require in-patient hospitalization.

So, in terms of the referral process from this point on currently until some time in the beginning of 2011, the way this works is that we have a continuity service that provides NNMC Warrior Care Clinic right there on our campus with the referral form, and then we actually have personnel that go back and forth between the two settings. The Warrior Care Clinic then fills out the referral form and includes additional records that are within the ALTA Medical Record System, which we are a part of at the NICoE.

Then we have a specific internal team made up of a psychiatrist, a neurologist, psychologist, social worker right now, and those individuals then look at that information and determine which of the group of patients referred might fit the program best and meet the criteria that I just mentioned. Those decisions are then discussed with the referring primary care provider in making sure we got the information that we really needed. Referral forms are being modified as we get feedback in this process because we want

to make sure we're actually making it user-friendly, if you will, and then the continuity service, we don't have another case manager group within the NICoE. We have people that are in a continuity system taking the service member from a case manager, handing back to a case manager, and not putting yet one more case manager in the system. We heard from the families early on, please don't give us yet one more case manager. We have eight or nine as it is, and so, we've decided how to make that transition as seamless as we possibly can.

We are then changing the forms such that they will ultimately be available shortly after the first of the year in a online referral form much like the Mayo Clinic as I recall, as I've over the years referred patients to Mayo. They have an opportunity for us to do that online, and it's processed internally. We've actually visited with Mayo to learn how it is that that's done on that end and try to emulate that here at the NICoE.

We have social workers, as I mentioned, that are continuity managers that work with that referral process, and then the interdisciplinary team works closely in determining the goodness of fit, then the warrior's command approval is very important within the military structure. We have to get them to the NICoE from wherever they might be around the country, and right now, the line leadership is very engaged in the process of how that's going to work, what the funding will look like, how the scheduling will work in their lives elsewhere, travel arrangements, and so forth.

As you know, there are a limited number of family members. I believe it's still just one family member that can actually travel with a service member for this kind of medical care. So, if we actually have two family members, which is the model we're after, it may actually require additional resources that we're investigating right now.

As the individualized treatment plan begins, that opportunity then for dovetailing with

where they're going back to is very important in this process and what treatment strategies will be available at that particular location need to be known right from the very beginning. And then we'll establish that long-term follow-up with those individuals after they leave. There's actually quite a large data server room in the NICoE which will house our own additional data for research purposes, but will allow us the opportunity to track individuals over a long span of time who've come through the building.

The evaluations that will be provided include a physical and neurological examination, psychiatric and psychological health evaluations, physical rehab, so, psychiatry evaluations, vestibular, as you can see. I don't know if I need to read this entire list to you, but the idea here is it's a very comprehensive both acute assessment as in let's see this for the first time even though we're getting records from outside or where they've been, but also expand it into a rehabilitation and long-term product care model,

if you will, so that we are as thorough and exhaustive as possible. It will include clinical pharmacy evaluations, spiritual counseling, nutritional evaluation, substance use assessments, and so forth. And we don't have all of these individuals onboard just yet even though we've begun our care process, but we will probably in the next four or five months have the bulk of that.

In terms of research, this is intended to serve as a collaborative research hub, leveraging advanced technical and clinical resources that we have internally and the environment for sharing across military systems, especially by the robust telecommunications and Internet connections that we have in the building. We'll also be designing and implementing pilot studies that look at the novel advances that we can create in the building with diagnostic and treatment strategies and serving as a knowledge source for evidence-based medicine and actually deciding what is the new evidence as we go,

building that forward so that we contribute to the literature in that regard as best we can.

And, also, we'll have a large database and specimen repository for bioinformatic analysis within the military system, and we are doing our best to make sure we're not redundant, but that we contribute by the gathering of specimen and by managing the interactions with existing systems around the DoD.

We'll be collaborating with Veterans Affairs, with DCoE, USUHS, NIH, Walter Reed, and so forth. One of the things that we've had a little bit of challenge around is the civilian academic piece because, as you all know, as the director of NICoE, I can't just pick a university as a partner. These kinds of opportunities have to be competed, and so, under those circumstances, we're a bit challenged as to how to move forward with that. There is some movement by a community organization to help us with a dedicated nonprofit foundation which would be able to serve that purpose and do the connections and creating those

collaborations, but as a military organization right now, we have the same sense of being confined and are certainly playing by those rules presently.

Our training and education mission is -- I should start here at the bottom, perhaps -- primarily aimed at the warrior and family members, and there are parts of the building that are specifically dedicated to teaching that service member about what happened to him or her and the family member so that the understanding is actually a big part of what they come away with. We've already heard from some of the service members in the two weeks that the very first cohort we had go through that they came to some ah-ha moment during that span of time. They actually concluded with this piece of it that's what the problem is, that's what's wrong here, that's why it's the way it is. This is where I need to go. Those sorts of awareness and insights because of the engagement with the clinical staff in this education process aimed at helping the

service members and families understand the problem. Really very powerful.

We will also have intra-professional staff development, team-building. The interdisciplinary exchange is a big part of this. I should explain that rather than the kind of thing I've typically had in the civilian sector where I have an entire team of all these different allied health professionals and colleagues, these people are actually part of a team in the same room at the same time gathering the information from the service member and family. So, when, in fact, they're sitting in this large living room-type setting that we have at the initial evaluation, the history is taken once rather than six or eight times in that span of time, and my team then gets to hear oh, that's what the physical therapist asks and why they want to know that, and that's what the social worker asks and why they want to know it. So, the interdisciplinary exchange amongst the professionals is enhanced under those

circumstances and efficiencies are brought into the process and the patient and family aren't annoyed by having to say the same thing six or eight times. Then we go off into the different things that we do separately and come back together working with that family in a collaborative fashion, but the interdisciplinary staff development is a part of the process. We don't pretend that we have it all figured out, but we're getting there and teaching that that kind of exchange is a big part of this model that we've crated.

Then there will be continuing education for existing professionals in the CME and CEU fashion, but, also, we'll be creating many fellowships so that military health system personnel from around the country can come and do a month at NICoE and learn this, take it with them, learn our protocols, create, perhaps, a different angle, bring with them their experience and teach us. We certainly don't pretend to have all of it figured it. And so, this will be a

collaborative exchange in that fashion educationally, as well. We will have certainly students, residents, and fellows, especially on that campus with USU and with NIH across the street.

There will also be a network of reach to the locations around the military health system. Initially, Arnold Fisher right from the very beginning in 2007 was saying oh, you need a bunch of mini NICoEs around the country. Let us help you figure out where you're going to build these. Well, those discussions went on for about a year, year-and-a-half, and the discussions led to the conclusion that that was not a good use of resources and it didn't dovetail with the military health system, especially at the primary care level, and what we really needed was to reach into the existing systems either with a virtual or telehealth, telemedicine reach or truly by going to these various locations around the country. And so, the idea is to have an extension of what it is that NICoE is doing at various locations,

especially the biggest military health systems.

Some of our sister organizations, if you will, within the DCoE, the other centers already have personnel in those locations, and, once again, we don't intend to reinvent the wheel or do something that's redundant. We want to work together with the existing systems, Defense and Veterans' Brain Injury Center in particular that has those locations around the military health system. The Center for Deployment's psychology has 20 psychologists around the country, and we will work collaboratively with them in terms of what they're seeing at their locations and the referral process and the follow-up process and so forth. So, this network, this web throughout the military health system from the NICoE, conceived of as the hub for that purpose should be a very efficient use of collaborative efforts.

And what I wanted to do at this point was just to show what the Smith Group, the architecture firm that created the NICoE did as a short -- I think it's about a three-and-a-half

minute video since I can't get you in the building at this meeting. So, perhaps some other time, we'll have that opportunity.

(Video played)

(Video malfunctioned)

DR. KELLY: Maybe you will just have to come and see it for yourselves. (Laughter) It's always something.

DR. POLAND: Does it look like something we'll be able to bring up or no?

DR. CLEMENTS: It's saying it's at the end of the video already.

DR. KELLY: Oh, well, sorry about that. It certainly isn't.

DR. POLAND: Maybe we should proceed then.

DR. KELLY: Yes, okay. How about if I just go? I think there are a couple more slides and some follow on for discussions.

(Video played)

DR. KELLY: Yes, it does look like, according to the time bar across the bottom, it

reached the endpoint. So, I don't think there's much else we can do at this point. I apologize.

So, at this point, I think what I'll do is open it for questions and discussion. I have a couple more slides that may come up as handy in terms of some more internal detail if I haven't already answered questions. But I apologize that you're not going to be able to get a good view of the building at this point.

DR. POLAND: Thank you. What an incredible resource for the military.

General Myers?

GEN MYERS: Right, Dick Myers. Great presentation. Thank you. Much needed capability in our system, and long overdue. Roughly seven years overdue, but we're getting there.

My question is on priority of the folks who come through there. How do you envision that working? Are you going to intervene while these people are perhaps still at Walter Reed or up at Bethesda or other places where they're first determined to have something like TBI? Are you

going to intervene there, or is it -- I mean, how aggressive are we going to be in identifying people to send to this center, I guess is my question. Probably not a question for you, but for the other medical providers here because this is an opinion, but I don't think we've been very aggressive in trying to identify people. So often, they'll get discharged and then the VA has to contend with them.

So, the relationship with the VA that you mentioned is also very important here, but how do you see that priority working? When is your intervention going to happen and how are you going to encourage people at Walter Reed to -- I mean, I assume they will be encouraged or at Bethesda to use your capabilities, these wonderful capabilities.

DR. KELLY: We are working, even earlier today, the integrated TBI leadership, the integrated system leadership and I met today with Captain Beaman to talk about some of these very issues about how that's going to work out because

there are places already doing the doing, if you will, of traumatic brain injury care. What we bring to it is that the psychological health piece in the same individual in a way that I'm not sure has been done before and needs to be done, in our opinion. And so, in terms of where they come from and how it works throughout the MHS, this institute, if you will, of the NICoE itself is not going to be a clinic and a solution for seeing lots and lots of patients in a high volume. It is intended to inform the system how it is that what we're seeing can be handled perhaps better, perhaps more urgently, quicker, picked up on earlier in the course of the problem and so forth before things get to the crisis point.

And so, one of my jobs that I'm absolutely thrilled about doing is going from place to place, especially the big military platforms, and talking with the line leadership as well as the health care provider leadership and the TBI Program specialists about what they see, what their needs are, what we can offer them, what

their problems are in trying to get services at the various places they are around the country, and it's a remarkable opportunity for us to communicate about this and then to say okay, your most complicated cases where you're just scratching your head and saying I need some guidance on this and I need some help, I need another opinion, whatever, those are the patients that we're asking for at the present time.

Now, the current thinking is that those will be people who are in that very small subset who have lingering symptoms that haven't been addressed or couldn't be treated already in the systems they're in. We may later find out that that isn't going to be really the best way to go, and what we really need is a very front-end, acute, new condition, new problem, okay, you go to NICoE and then you go to some other location. So, what we're really looking at right now is to try to help those individuals that we keep reading about and hearing about as I go around the country who have lingering symptoms and they say we've

tried that, we've tried that, we've tried this, and nothing has worked. Your turn. You figure it out. So, right now, that's the approach we're taking, and for many of these people, it's months down the road after their return from a deployed location. It may be that we need to morph generally into some other approach.

GEN MYERS: I guess what it leaves out is that population has been discharged that has the issue and are at the mercy of the system, whatever that system is, or might not even know why they are the way they are. So, I know it's not in your scope, but one of the questions, because I think it is in your scope, my assumption then is that you have had some contact with this MIT collaboration initiative that ASD Health Affairs has funded.

Are you in touch with them?

DR. KELLY: Yes, the Summit Program.

GEN MYERS: No, no, it's a recent program that I assume other people know about, but it's --

SPEAKER: Dr. Tenley Albright.

GEN MYERS: Tenley Albright and Ken Caplan up at MIT, are you --

DR. KELLY: Yes, sir, we are involved with them, as well. Yes, sir.

GEN MYERS: Because what you're doing is -- they've got to know what you know because it's going to be part of their more extensive study.

DR. KELLY: We're already hooked in. Thank you.

GEN MYERS: Great. Perfect.

DR. LEDNAR: Wayne Lednar.

DR. KELLY: Hi, Wayne.

DR. LEDNAR: A question, as you've emphasized in your concept the importance of family to be involved in the care planning and care delivery. For a number of these young service members, their family is their squad, is their platoon. So, I'm wondering how your concept will incorporate how their military units, who they spend a lot of time with, can become part of the next step after they finish at the NICoE.

And then, secondly, as you travel to these various MHS facilities, do you feel like you're able to get an approach which gets beyond the usual medical, surgical silo and really gets across discipline approach to these patients where not just the medical needs, but the psychological needs of the patient are part of the care plan once they get to their next installation.

DR. KELLY: To your first question, we have defined "family" in the broadest sense we know. It's who the service member thinks of as family. And so, what we struggle with is what happens if somebody can't bring anyone, and we don't have a solution for that just yet. Right now, the patients that have come since the Fisher House hasn't been available, are coming from this part of the country right now, and they travel in each day either from Walter Reed or from some other location where they're residing while they've been getting their care in this area and are being handed off to us. And so, the Fisher House isn't online, and so, we don't have the

families with them.

We will be very shortly at the point where we'll be using that Fisher House for the families, as well. So, that the service members come by themselves, and we've already engaged that individual, and the families then are individuals either true, biological families, family members, or individuals close to them in their lives that they bring in for wrap-up sessions and that sort of thing. So, we are going to have to be creative as to how it is it works for given individuals who don't have family other than their identified peer group, and that's something we're going to need advice about.

As to the MHS piece of it and the questions about how it's received out there, the opportunities for what's available throughout the MHS are so widely variable, as perhaps you know, that there are some locations where we simply don't have the opportunity to send patients -- I can't imagine sending them back to certain locations because of the paucity of resources in

certain locations. And what I've been trying to do, and this is one of the things with Arnold Fisher not exactly whispering in my ear, but saying things to me, bring the academic community into those locations as best you can, and that's something that so many of the military leaders have asked for, as well.

And so, when I went to Fort Hood, for instance, I brought the lead neuropsychologist from the University of Texas-Southwestern in Dallas down so that he could be there for the day with me to engage with him to determine how could his university help under the circumstances of the very limited resources that are available in Killeen, Texas? We did the same thing at Fort Bliss. Fort Carson has University of Colorado. Fort Camel has a very sophisticated connection to Vanderbilt. And so, some places have already made those engagements and connections, and at those locations, they actually have elevated the level of sophistication that we can actually deal with in those centers, and, in many cases, learn from

them as to what it is they've already created and how it is they've been functioning in that setting. But it's widely variable from San Diego to Killen, Texas. I mean, it's just a huge difference in terms of available resources and programs.

DR. POLAND: Dr. Kelly, I understand you have another three slides or so you want to show. I know one of them is on research. When you show that slide, could you give us maybe just a brief background on what the research infrastructure and budget will be, or do you have to go out and compete for those dollars?

DR. KELLY: As it stands right now, we do not have a fixed research budget through the RTD&E process, but we are working toward getting that as a piece of what happens and then separately we're looking at philanthropic and potentially appropriations from Congress that would also be aimed at research that we will direct form the NICoE itself.

At the present time, we're actually in a

bit of a bind. So, for me as a civilian, government employee at the NICoE, I could not serve as a PI on a grant that was a DoD grant because I wasn't considered to have an internal influence, if you will, or that kind of conflict of interest bias that my position brings to that very process. And so, I'm boxed out from participating in the competitive process for the NICoE because I'm at the NICoE. And so, we have to be a little bit more creative as to what those solutions are.

Now, other individuals have already brought in the National Capital Consortium TBI Neuroimaging Project. Actually moved from Walter Reed over into the NICoE when the PI brought it with him, and we were able to work that piece out, but it already existed in that setting. And then we are the data repository or we will be the data repository for the big hyperbaric oxygen protocol that will start up after the first of the year.

So, again, our data-gathering system, our neuroimaging piece is actually a part of that

study. The outcomes assessment center that's in the Town of Colorado Springs outside Fort Carson and the neuroimaging and rehab piece that actually are on post. The data that's gathered there will then sent to the NICoE, and we will participate under those circumstances with that funded research. As we get down the road a little bit farther and we have other streams of research dollars, we'll be able to build our own.

DR. POLAND: Dr. Silva?

DR. SILVA: Joe Silva. You only have to concentrate on mild and moderate. Or I don't mean "only." It's a big load. What's going to happen to those that have advanced or severe levels of these problems?

DR. KELLY: Right now, the model typically is that the severe traumatic brain injury care that's provided in the big hospitals, Walter Reed, National Naval Medical Center, and then Brooke Army Medical Center, although, certainly, it can be done in other locations, those individuals receive the acute care there.

Walter Reed has a rehabilitation piece of that that's been around for years, and the Defense and Veterans' Brain Injury Center works more closely with that than to bridge to the VA System where the rehabilitation can be ongoing and much more long-term. So, that's actually farther along and more sophisticated in the care, especially for penetrating brain injury in this current conflict is superb. I mean, it's truly advanced significantly from where we had been in the civilian sector and so forth just years back.

We all need to learn about mild traumatic brain injury. We don't have even well-accepted protocols in the civilian academic world for how to treat this. There are multiple things that have been tried and we will be, again, one of the places where this experimentation, if you will, is implemented. But the huge numbers of individuals with that problem and with a combined psychological stress profile and TBI together is a whole new problem that these conflicts are bringing back into society that we just haven't

deal with before. And I think we're doing our best to push that forward.

DR. POLAND: Dr. Shamoo?

DR. SHAMOO: Jim, as usual, great presentation, as well as this is an incredible resource to our country.

It's going to be very highly sought after facility by those who have those problems of TBI-related problems. How are you going to select so few from literally tens of thousands of potentially complicated and the clinical care is really not well-defined yet.

DR. KELLY: We do anticipate that being an issue and a concern, and, in fact, as we look at those that we think have the most complex and complicated courses, we actually then are filtering out many, many others that perhaps can be dealt with if, in fact, you take a piece of what is available at one military location and then bring it to another where they are, and they don't need to come to NICoE. And so, we will actually engage in those discussions ahead of time

with the providers and say gee, why don't you contact so-and-so at this location, see what they're doing with this very same problem, and see if that would help under the circumstances?

So, once again, if you look at the numbers, we're going to, when fully operational, see about 500 patients a year. Right now, that doesn't sound like a huge number, but if you actually look at all the data points of what is we're gathering and how it is that these complex conditions will be understood better, we will then be able to discuss that more broadly throughout the MHS and influence the system. That's the entire intention here is to be that rising tide that lifts all boats, not just see patients. It's not yet one more clinic; it's truly a DoD institute for this problem.

DR. SHAMOO: So, what's the selection process? What is the decision-making process, because there will be potential problems among those patients and how you're going to make the selection. Do you have a flow chart, do you have

a committee, do you have something?

DR. KELLY: We have now there will be a board of advisors within the DoD leadership in Health Affairs and within the surgeon general ranks that actually guides that thinking and collaborates with their systems in each of the services so that the decisions as to quotas perhaps or which locations and all that sort of thing will be decided not just by us idiosyncratically, but by the military leadership.

DR. POLAND: One more question, and then I think we'll stop for lunch.

DR. MASON: A repast. Tom Mason. Just a quick question, picking up on what Dr. Shamoo has just alluded to and in on of your slides when you refer to your follow-up metrics, could you give us some indication as to how many times these individuals are actually going to be seen, leaving aside your clinical interventions at NICoE. Because you have 500 persons per year. With what regularity, on what schedule are they actually going to be followed-up? Who does the follow-up?

Because 500 persons can be large enough to address certain things depending upon how many times you're going to see them over a span of 6 months, 12 months, or 18 months. Has that been worked out at all?

DR. KELLY: It has been discussed. We haven't settled on it just yet. If you use the civilian model, it would be one month out, and then six months out, and then a year from that, and I'm not sure that that's enough under the circumstances, and it sounds like you might agree. And I think that the level of granularity of our assessments in follow-up is going to be important, too. It's not just a matter of return to duty or not return to duty, it's not just functional independence measure and things like that because we're dealing with a completely different population than measures like that were intended for.

DR. POLAND: Okay. Thank you very much. Appreciate you coming.

DR. KELLY: Thank you.

DR. POLAND: Incredible information.

DR. KELLY: Thank you all. (Applause)

DR. POLAND: We're going to break for lunch, and Ms. Bader will give us some admin on that in just a moment. I will ask the members of the ID Subcommittee to meet at the far table in the room where we're having lunch.

Ms. Bader?

MS. BADER: Thank you. We will now break for lunch. An administrative session will be held next door where we had breakfast this morning. So, we invite the board members, ex-officio members, service liaisons, and DHB staff. Also, our distinguished guests. Catered lunch next door. I made an announcement earlier this morning regarding other places to eat for our guests that are not part of the official group, if you will.

So, we will reconvene at 1:15. I'd like to ask Dr. Shamoo, did you want to meet with your Medical Ethics Committee during lunch?

DR. SHAMOO: Yes, yes, at lunch.

Please.

MS. BADER: Okay, so, Medical Ethics Committee, please look for Dr. Shamoo. He'd like to have a small meeting during lunch. And we'll see everybody back here. And Dr. Halperin would like to meet with his group, as well. So, and we will meet back in here at 1:15. Thank you.

(Whereupon, at 12:08 p.m., a luncheon recess was taken.)

A F T E R N O O N S E S S I O N

(1:17 p.m.)

DR. POLAND: Can we have everybody take their seat, please? We'll get started. We're running a few minutes behind schedule.

Is General Volpe here? We're missing the -- oh, okay. Okay.

Our first speaker this afternoon is Major General Philip Volpe. He serves as the commanding general of the Western Regional Medical Command and senior market executive for TRICARE Puget Sound. He's a board-certified family medicine physician, and was selected as the uniformed services family physician of the year in 1996.

Major General Volpe most recently served as a deputy commander joint task force National CAP region medical at Bethesda Naval Base. He additionally served as the operational medicine consultant to the Surgeon General from '98 to 2003 and is co-chair of the Department of Defense task force on suicide prevention by members of the

armed forces.

Since the Board issued its guidance and endorsed the findings and recommendations of the task force during the meeting held on July 14th earlier this year, the task force has produced a final report and delivered it to the Secretary of Defense. Major General Volpe will provide an update on recent activities regarding the task force report, and I believe his slides under tab 4 -- I'm just going to ask Ms. Bader to make one comment before the General starts.

MS. BADER: Sure. I just wanted to let everybody know that the task force had their last meeting a couple of days ago in the Washington D.C. area, where they gathered to conduct basically a hot wash, if you will, and look at some lessons learned. General Volpe will talk about that a little bit.

But just I wanted to make everyone aware that on behalf of the Board and the vice presidents, each task force member was presented with a coin from the Defense Health Board and a

letter of appreciation from Dr. Taylor, who is performing the duties of the assistant secretary of defense for health affairs.

Thank you. General Volpe?

MGEN VOLPE: Great. Well, thank you very much, sir, ma'am, the entire Board. Thanks.

It's good to be back again and brief you. I am Phil Volpe and Ms. Bonnie Carroll is the other co-chair on the DOD task force on the prevention of suicide by members of the armed forces. And Colonel Joanne McPherson at the end down over there is our executive secretary, who many of you have seen at multiple meetings.

We've briefed this Board many times before. IPRs, if you will, along the way of the deliberations of the task force. Prior to us, publishing the report and then we briefed you right around the time that we published the report.

And this is a follow-up to just basically discuss our activities since that time, now that the Board has completed -- now that our

task force has completed its mission and its responsibilities and has essentially been disbanded as a task force at this time.

So if we could go on to the next slide, please. As you all know, we met from August of 2009 to August of 2010 with the charge of the task force is to make recommendations to the Secretary of Defense on a comprehensive policy to prevent suicide by members of the armed forces. This was directed in NDAA '09, and that was why the Secretary of Defense organized and created our task force. Next slide.

Well, we completed our mission, as you know, and submitted our report. Now, we had briefed the Defense Health Board a month earlier. Our initial plan was to release the report on the 5th of August, and we took a couple of extra weeks because the task force felt that -- actually, the input from the Defense Health Board was very critical to make sure that we included. And so we actually -- we made some modifications to include many of the recommendations that this Board had

made to us in the July timeframe and had met on many occasions between that July and August timeframe.

We also conducted a press conference, but the report was submitted to the Secretary of Defense on the 24th of August. And that was -- that completed the mission of the task force. Many of you have seen the report. I think we sent a copy to each of the members of the Defense Health Board and had seen the roll-up, including the executive summary towards the front of this. And a whole bunch -- a whole slew of appendices to support the information that we provided in there. But there were 49 findings, 76 recommendations, and then many of those recommendations were aggregated into what we considered 13 foundational recommendations. And those have all been in the report and briefed to this Board previously.

Since that time, we've gotten a lot of requests for briefings. And even though our task force on the prevention of suicide has been disbanded or has concluded, you know, we will

always make ourselves available to brief what's in the report and about the report and the findings and recommendations and our thinking process and deliberations about that. We just feel that that's our duty, and every member of our task force has agreed to do that, regardless of where they are located and the individuals -- and the groups and individuals that request us to conduct those briefings.

We have -- I felt very confident we've kept complete transparency the whole time and did not hold anything back as far as the deliberations go and what we placed in the report, and that we were, as an independent task force, were uninfluenced by any outside body other than the -- you know, recommendations from experts out there on, you may want to look at this a little differently and input here and there. So it's been very -- I'm very confident about that.

On 8 September we briefed the Wounded, Ill, and Injured Overarching Integrated Product Team at the Pentagon. We also had a meeting with

the DoDIG, and that had to do specifically with the investigations portion -- standardizing suicide investigations across DoD, because the DoDIG is the primary office that considers all investigations within DoD and writes the regulations and policies that the services follow on that. And so, they were very interested in what we had written in there and, again, we went into open discussion with them at that meeting.

And then we briefed on 17 September the Wounded, Ill, and Injured Senior Oversight Committee, headed up by the Deputy Secretary of Defense and the Deputy Secretary of the VA. And we briefed our summarized findings and recommendations in each of our four focus areas as we have outlined them in the report, and so that they fully understood what our report said.

On the 23rd of September, we were involved -- and we will continue to be involved -- with briefings to audiences, you know, webinars, seminars, and those kinds of things in conjunction with other bodies that have also investigated or

reviewed suicidal behavior and suicide prevention and have made -- have additionally made recommendations with their expert bodies along the way. And the RAND Corporation is one of those who have provided a report, and there's other organizations out there, too.

In reviewing all of these -- they're very consistent and collaborative. Each has a little unique twist and focus area, a little different, in suicide prevention. But overall they're very complimentary of each other, these various bodies.

On the 7th of October, we had a great session with Admiral Mullen in the Pentagon and his staff. The chairman is very interested, as in all the service senior leadership are interested in suicide prevention. Very much concerned about the number and rate of suicide and what we are physically doing on this. And Admiral Mullen basically gave his staff -- charged his staff to look at what current recommendations in the report -- what recommendations in the report can we do

right away. Because he sees this as a crisis and believes it will get worse, the suicide rate, before it gets better. So looking to start implementing our recommendations right away and seeing how he could use his influence within the Department to make that happen.

October, we also had a meeting with the Deputy Undersecretary of Defense for Readiness. And this is key, because the Deputy Undersecretary of Defense for Readiness is one of the individuals that would be involved with one of our recommendations that we established as DoD suicide policy division within the Undersecretary of Defense for Personnel and Readiness. And so, they already appear to be linked in, getting background information, asking the right questions, reading through the report, and looking also at writing the response that the Secretary of Defense will provide to Congress as DoD forwards our report up to Congress. And I will talk about that in a second.

On 21 October, we had an opportunity and

briefed the Defense Senior Enlisted Leaders' Conference. All of the senior enlisted from around the services and the combatant commands were at the Pentagon for a semi-annual conference that they do and they requested that we brief them on our findings and recommendations for suicide prevention. And we focused it on that in Senior Enlisted Corps, and some of the things that we saw that would be beneficial for them in their suicide prevention programs through their organizations and units around the Army, Navy, Air Force, and Marine Corps.

On the 28th and 29th, as Colonel Bader mentioned, we did the task force hot wash. Two focuses of this hot was were, I wanted to make sure that before the task force completely disbanded, that we picked up some lessons learned. So we're actually going to publish lessons learned about everything from putting our task force together to our methodology in producing the report, some of the things we learned along the way, clinically and operationally of the task

force, and provide that to the Defense Health Board and to DoD Health Affairs in case any other future task forces would be interested in seeing some of the lessons that we learned in our deliberations and how we went about with our methodology to produce this report in a one-year timeframe.

So, we decided to do that. And then we also wanted to make sure we aligned up our strategic messages appropriately, because we believe that there'll be ongoing interest in requesting members of our task force to either be parts of other task forces or communities or subcommittees, or organizations within DoD and outside DoD on suicide prevention. And additionally, we are anticipating that at some point we may very well be summoned to testify before Congress, since this was generated through the NDAA '09 from Congress to establish this task force in this process. And if that came, it probably would be after OSD or the Secretary of Defense would submit their -- his response or

DoD's response to our report, which is due to Congress somewhere around the 24th of November of this year. So, sometime at the -- towards the end of this month, which is 90 days after we submitted our report, was the requirement.

And then we've already been requested to speak at the VA-DoD Suicide Prevention Conference as part of a panel. Suicide prevention overall between the VA and DoD in the future. Next slide.

Okay. I mentioned the report. You all have it, and in that report I said it's a pretty thorough recommendation of our findings and recommendations. And a whole lot of background and supporting material that is in there, and our approach and methodology to publishing this report.

I always -- I mentioned those 13 foundational recommendations. But there's three takeaways we always brief for members of the task force that we brief. And one of the large recommendations that we have made is, these three recommendations, particularly, are considered by

our task force as not only key foundational recommendations but must be addressed and is sort of a little unique or different from other task forces and bodies that have looked at suicide prevention who have focused more internally into the services.

And one of them is to establish a suicide policy division in the Undersecretary of Defense for Personnel and Readiness. There currently is no full-time staff body that looks at suicide prevention in all of DoD. It is entirely embedded within the services. And there is no one to get resources for the services to standardize nomenclature, standardize reporting procedures, standardize investigations, and to help collaborate with advisory bodies outside DoD as suicide prevention unfolds in the future. And so that was a large recommendation that we had made in there.

The second one you see there is to reduce stress of the force. Our task force clearly found a supply/demand mismatch on the

force. What we found was just absolutely amazing that our servicemen and women -- remarkable. They're remarkably resilient, but remarkably take on the mission and do what they're told and, patriotically, and loyal, regardless of what the task is ahead. And we utilize them a lot for the national security of the United States and they, you know, bear the burdens that come along with that. The physical and psychological damage that occurs from meeting those demands.

And I use the word "damage" because lack of a better word. But it's this accumulation of stressors, repeated separations with families, repeated disconnectedness, putting your life on hold for deployments, and then repeat deployments. And the overall OP tempo and stress on the force. And a lot of the things that are in the Army suicide prevention report specifically address that same topic as well when they talk about the lost art of garrison leadership. There isn't quite enough -- the same amount of time to do all the mentoring and coaching and leadership

oversight -- professional development that we were doing at one time before these wars started, because there's so many tasks and things to do to support the fights downrange and the missions that we're churning and burning and going over and over.

So, this was very important to acknowledge that there is stress on the force and it's fatigue. And again, it's remarkable what our men and women do that, you know, I -- the term out there is "suck it up and drive on." But, you know, they do what they're told to do and it's absolutely amazing, regardless of any barriers or anything in the way.

And so we owe it to them to look at suicide prevention and everything we could do to help them normalize their lives again, both physically and emotionally, and spiritually and psychologically as they return and meet the missions for our nation.

And then the third point there in suicide prevention is a leadership issue. And

this was very important because it tends to be tucked into the medical community in a lot of places, but it is clear that it is a leadership issue.

Now what we saw in our task force that strategic leaders are very much engaged. But then it starts to disintegrate as you go down to junior leader positions. In other words, junior leaders and mid-grade leaders aren't as well-versed and engaged in suicide prevention because of the op tempo and everything that's -- all the demands on their plate from day to day, as our strategic leaders are. And we have to find a way to make time to get them more engaged and create those positive command climates where it's going to make a difference. The small unit level is where it's going to make a difference. And so it needs to stay in the leader's lane, not in the medical lane. We could never underestimate the impact of leadership on suicide prevention, or anything else that we do. And I think we've known that pretty well throughout the history of the United States

military.

And we also clearly saw the difference of very positive, engaging leaders who get it and the differences in the outcomes of their soldiers, sailors, airmen, marines. And we've also seen the effects of leaders who are not well-enough trained, junior leaders who are not well-enough trained, prepared, to deal with those difficult human things that occur to people along the path. And/or negative command climate or toxic command climate, whatever the term is, and its impact on suicide prevention.

We still hear today stories -- I get e-mails all the time -- of the junior officer or the junior NCO that stands in front of their formation and creates the impression or belief in their -- in the folks in their charge that it's a weakness to seek help and/or, you know, you're not a good warrior if you have these weaknesses or those kind of things. And those messages need to change at the junior level. There's still that perception out there. As well as the stigmas that

go along with -- not only in suicide, but behavior health in general out there.

So, we always use these three key takeaways as our really strategic messages that we want to get out there on there. And that suicide is preventable, and having any of our nation's warriors die by suicide is unacceptable. It's unacceptable. Because we get asked that all the time, what is an acceptable rate? Well, I don't think we should establish an acceptable rate. Many people say, well if you're below the civilian rate, you know, is that an acceptable? Well, we shouldn't look at it that way. We should try to prevent every -- we should put our best effort forward for our men and women who are serving in uniform to prevent suicide to the maximum extent possible. Next slide.

All right. Then I'll open it up to your questions and you can see on the bottom there is our link to the report. Everything is out in the open. There's nothing hidden or whatever that you need to do. We're completely transparent. So,

link to the report and also the press conference in there.

And we'll continue to provide the press with information as they request information, too. Because our strategic messaging is very important, and is also in our recommendations -- foundational recommendations on suicide prevention.

So, sir, with that in mind I'll be happy to answer any questions.

DR. POLAND: Thank you very much. Dr. Kaplan?

DR. KAPLAN: Thank you very much, General Volpe. Back to the second to the last slide where you talk about the SECDEF submitting the report to Congress and then congressional requests. Do you anticipate that the report will in any way result in congressional hearings or congressional action? Or will it -- or do you anticipate that it will be up to DoD to take action on this very complete report?

MGEN VOLPE: Yes, sir, thank you. Well, first, it is up to DoD to take action on the

report. But I believe that there will be significant interest, especially if the rate remains the same and/or goes up. But I think there will be significant interest at the congressional level, simply because they were the ones who put it in the congressional language to create the task force.

But also because they're -- they have ongoing testimony now from all of the services on suicide. I think it's all mixed together, but testimony on suicide prevention, post traumatic stress disorder, and traumatic brain injury. It's sort of lumped together right now for the services to testify.

So I believe that once the Secretary of Defense OSD provides their response to our report, that there will be -- and we're anticipating that we, members of our task force, will be summoned to testify, too, at some point. I mean, all we can really do is just anticipate that, be prepared.

And we will -- and basically our role in that is to stay with and talk about the report

itself. What's in the -- because that was our duty was to make these recommendations and why we made those recommendations.

DR. KAPLAN: Thank you.

DR. POLAND: I'll ask Mr. West if he wants to make any comments in regards to this.

MR. WEST: Okay. Thank you, Dr. Poland. Thank you. And for the report and for the hard work that went into it and for your discussion just now.

Let me ask you a couple of things that I think you touch on in your report, but I just like to hear your comments on. A collection of measurable indicators that as they either go up or down, you'd think you can also detect a rise or fall in the rate of suicides.

Let me give you an example. OP tempo. As it goes up, the -- I think your answer pretty much suggested by your report is there's a whole bunch of factors. And so just one going up might be compensated by others. But that's an example. Or this one, numbers of chaplains per service

members. I mean, is there a collection of those things that if we looked at measurable indicators -- not discussable indicators, measurable ones. That as they fluctuate you will see a discernable change in the rate of suicide?

MGEN VOLPE: No, sir. That research hasn't been done to provide a source to create metrics to measure those sorts of things. And that's one of the reasons why in our report we recommended supporting further research in the area. And there is research that's going on there.

What we did find, though, as a measurable -- I don't know if it's measurable from a quantifiable standpoint. But measurable was that service members, their perception of behavioral health, seeking behavioral health -- help-seeking behavior -- is a lot better when we embed behavioral health individuals and chaplains in units with them. They establish relationships, the barriers are down, and they tend to seek those individuals when they're having stress-related

problems or other problems in their life which maybe put them at risk for suicide. So that is a recommendation that's in our report that the services should heavily study embedding more behavioral health personnel with the troops in various activities.

MR. WEST: Okay. Thank you. And then this second one, which I leave to you to consider personally.

Taking into account your recommendations and the obvious interest, what do you expect to happen as a result of your report?

MGEN VOLPE: Yes, sir. What we expect to happen is to see the development of an implementation plan. And that implementation plan includes those 76 recommendations.

Now I will tell you that one of the things, sir, that has been going on because of our transparency during deliberations, we've worked with the services throughout our deliberations and briefing and sharing information. And many of these recommendations are already being considered

by the services and they're already, you know, developing their particular programs or response to those recommendations on there.

So, you know, our hats off to the services because they're already doing a lot. They've been doing a lot. But one of the recommendations -- one of the findings in here was that one of the difficulties we've had while they're doing a lot for suicide prevention, no one has ever taken the time to do just what you just said, sir. And that's build in program evaluation to know which programs are working and which are not to get the outcomes for suicide prevention and the results.

And so thus, they're doing a lot but nobody really knows which programs are good or not or working or not. And so, the services are looking hard at that right now with their current programs and also developing new initiatives based on our recommendations.

But an implementation plan by DoD, I would think, where they list each recommendation

and say which ones they'll accept, which ones are short-term, which ones are mid-term, and here's how we're addressing each of these recommendations and how we'll look at it.

But again, I think our first recommendation is probably the most important. And that is, to establish a full-time office of folks that do nothing but look at from a suicide prevention policy division. We specifically said "policy" because the programs still need to be with the service. The service secretaries and the service chiefs and their Title 10 authority, they need to run their programs for their service. But there is, certainly, ripe and beneficial to share best practices, have standardized reporting procedures and measuring tools, and those things, and also to get resources for the services for the suicide prevention programs. But having a policy division at the OSD.

Yes, sir.

DR. POLAND: I have a comment for you to consider and then follow up with a question. And

let me take a run at this. I think I've talked with you once before about it privately. But let me flesh out the idea publicly.

You mentioned, and I completely buy the idea of suicide prevention being a leadership issue and how it's necessary at the small unit, really junior leadership level, to start inculcating that in the command climate.

And an exponentially efficient way that I can think of in terms of beginning that task is to utilize our service academies. The interesting thing is, we have the collocation of behavioral science departments capable of teaching in research and 16,000 of our nation's future leaders, all of whom from hour 1 at one of those academies began to experience stress and challenge that is unique in their lives. And they begin to develop a perception of how you deal with this, or of how, as one cadet told me, well if this was a serious issue they'd be teaching us something about this. If they were serious about it.

So -- and when we were at West Point I

talked with the woman from the behavioral science department who briefed us. And then Labor Day was Parents Weekend at the Air Force Academy. Several of us have sons or daughters that are at the academies. Ms. Bader has sons in each of two academies.

So, my daughter is a psychologist. She and I briefed the major findings of the task force and then results of some of her research to the medical clinic command there and to the behavioral sciences department. So both the Air Force and West Point eagerly latched onto this idea.

About four weeks after that, one of the senior cadets at the Air Force Academy took his own life. Within 12 hours, a second was intercepted and fortunately was not successful. So, this is an immediate, acute, sharply-felt issue and I just think that, you know, in a 4-year cycle you will have sent 16,000 leaders out. By this time next year, you would have 4,000 second lieutenants out there who could be informed by a curriculum and an understanding from the very

beginnings of their military career how important this is to them as a future commander.

So, just a thought. The second is a question. I heard a snatched on the radio, I believe, that -- maybe it was the Army. But a large grant or research project had been funded on the order of 17- or more million. Am I right about that? Or, maybe it was funding of a program in suicide prevention? Anybody aware of this or had heard anything?

MGEN VOLPE: Joanne, do you know?

MR. DANIEL: Sir, Chris Daniel from Medical Research and Materiel Command. As you probably know, the majority of the psychological health research either through the Defense Health Program or through the Army is coordinated at Fort Detrick. And I think what you're referring to was the announcement of an approximately $17 million effort. It's a consortium, I don't have the facts with me to specific members of that consortium. But it will focus over the next couple years on really the epidemiology and the -- as you know,

there's a lot more research that's going on. But I think it will address some of the things that you, sir, talked about in terms of the measurement of the effectiveness of a lot of the things that have gone on. But it's really predominantly focused on epidemiological work as opposed to the actual programs themselves.

But if you want even further information, I can try to get that back to you. But I can at least tell you that you were right that within the last week that's been announced.

DR. POLAND: Okay, thank you. My final question, then, seeing no others is, is there anything more the Board can do to help? You have, and your committee, have brought -- I guess the word I would use is a lot of vitality to this issue. And really, have done it in a very scholarly and yet feasible set of recommendations.

Is there anything more we can do to sort of keep this up on everybody's radar screens?

MGEN VOLPE: The only other thing I would say, sir, is to look at a mechanism,

possibly through one of the subcommittees here on the Defense Health Board? Specifically to look at the healthcare portions of the recommendations that we make in here. Because remember I said suicide prevention belongs in the leader's lane, not funneled into the health care lane, per se. But health care -- behavioral health care -- is an important component of suicide prevention.

And we make a number of recommendations that have to do with behavioral health, the continuity of behavioral health, the documentation, management during transitions, and even training programs for behavioral health personnel to get them up to speed. Because as you know, one of our recommendations was just because you have a degree on the wall in psychology or psychiatry does not make you qualified to understand suicidal behavior and suicide prevention. You need additional training in that, in those kinds of things.

So I -- my recommendation would be now that our Board is -- has completed its mission and

is disbanded, that in order for -- that it would be useful for the Defense Department if the Defense Health Board continued to track this and possibly track it -- the medical portions of it, the health care portions, behavioral health portions -- through the mental health subcommittee.

And of course -- and if you needed experts on suicideology to be a part or an advisory to that, our members are -- we want to make a difference. I mean, our goal is that we prevent suicide. Save lives, prevent suicide. And strengthen the force while we're doing it.

DR. POLAND: It's an excellent suggestion. We will do that.

MGEN VOLPE: And so, that would be it.

DR. POLAND: Charlie first, and then any other members of the Psychological Health Subcommittee that want to offer any comments?

MR. FOGELMAN: Well, I think there is only one other here.

Would be happy to take that up. But

don't we have to be asked a question? This comes back to the continuing issue of what it is that we talk about and what the products of the subcommittees are.

If you could give us two or three specific policy or program questions you'd like answers to, we'll follow up on them. It has to come through the board, I guess. Greg will tell you how this has to happen. Then we can do it. Otherwise, we're always happy to talk to people and engage. But if we're going to have a product we need to be asked for a product.

DR. POLAND: Bill?

DR. HALPERIN: Maybe just one other --

DR. POLAND: Your microphone.

DR. HALPERIN: Sorry. Bill Halperin. Maybe there's one other follow-up.

One of the focus areas is surveillance and investigations. So, perhaps, you know, with your help if we knew more specifically what surveillance of what entities, et cetera, that we could track that as we continue our engagement

with the deployment health surveillance centers and research centers and so forth.

But it has to be more specific than just sort of the broad area of surveillance. What specifically did the group want to see? And then as we go do our evaluations we can find out whether this is forthcoming.

DR. POLAND: Good point. Okay, Bob, did you have any comments you wanted to make? No?

COL CERTAIN: Not right now.

DR. LEDNAR: General Volpe, first thank you to you and Ms. Carroll and Colonel McPherson for all the leadership that you've brought to this issue in really 12 months. Accomplished really quite a lot.

As I'm thinking back to all of the levers that might be pulled to improve this issue, I think back to what our warriors faced from those returning from Vietnam. And into communities that were not welcoming to the service that they provided.

As your task force did its work, do you

see an opportunity for the communities -- not only on post but around our installations -- to do things in a way -- it might include their employers -- to be supportive to this issue we're trying to get better at?

MGEN VOLPE: Yeah, but I mean, let me say first of all, our communities are very supportive, I think, around the country for military members -- all components -- and their families. I think it's more of a thing that they may not know how to better support or not empower, to support certain aspects of it.

So there are certainly that could be done in communities -- particularly for the reserve component, who don't live near our camps, posts, stations, bases, and stuff. Where we can help educate and empower the religious community, the various chaplains of different denominations on what to look for and what to see in service members that have been demobilized that live in their communities. On how to recognize it and how to get them back into a helping professional that

can do the care. The same thing with behavioral health individuals out in communities and stuff. Understanding what service members do, the demands on them, and what to look for, and stuff, I think, would be very valuable.

So, I think it's more of an education, knowledge -- empowering them, making them better at helping our service members. It's not a matter of will. They all want to and they're all very supportive of our servicemen. And I don't know if that answered your question, but.

And there are ways -- I mean, I know of there's an organization called the Citizen -- it's called the Citizen Soldier Support program. But it's not just soldiers, Army. It's all service members. And they focus mostly on what communities could do to better support the military out in their communities and stuff. And it focuses a lot on healthcare and it focuses a lot on spiritual assistance, too.

DR. LEDNAR: Thank you.

DR. POLAND: I had asked my question

about what more could we do hoping to hear the sorts of comments that we did, and I think we will further work the issue. We have assets in our own subcommittee structure where we can sort of keep this alive and push on this a little further. We can answer specific questions and will endeavor to do so.

So, thank you very much for your leadership on this.

MGEN VOLPE: You're welcome. And we'll be happy to brief -- anyone with any interest we'll be happy to brief individually and sit down one-on-one about the report and some thoughts on this, or as a group, so. (Applause)

DR. POLAND: Okay. Dr. Dinneen is not going to be here, thanks to Hurricane Thomas. And he's stranded on an island somewhere, so maybe not a bad place to be stranded, I don't know. Depends on how fast the wind blows.

So we're going to move right to Dr. Halperin's portion of this. As you know, Dr. Halperin serves as the chair of the Military

Occupational/Environmental, Health, and Medical Surveillance Subcommittee. And in addition, he chairs the Department of Preventative Medicine at the New Jersey Medical School as well as the Department of Quantitative Methods for the School of Public Health at the University of Medicine and Dentistry of New Jersey.

Dr. Halperin has formerly served as the chair of the Committee on Toxicology of the National Research Council, and is certified by the American Board of Preventive Medicine as a specialist in occupational medicine, as well as general preventive medicine and public health.

His experience in epidemiology ranges from field investigations of outbreaks to more subtle investigations of the association of chemical exposures with a variety of outcomes, as well as occupational injuries. His presentation slides are under tab 6.

And while we all know and love Bill, let me just say my personal thing that I'd like to commend Bill for -- as is true for many of our

members. Even in areas far afield from his expertise, he listens very carefully and you always know Bill by the very thoughtful, insightful, and scholarly questions that he brings to bear on any topic. And I've just personally appreciated that about you, Bill.

So, the podium is yours.

DR. HALPERIN: Well, thanks, Greg. Sort of jack of all trades, expert at whatever.

Yes, and I'm also retired from the U.S. Public Health Service, where I served for 25 years. And I have absolutely no idea how to use this gizmo. How do you -- okay, so that's how you use it. Okay. So if you go there -- so, this goes forward? Yes, it does. And it goes backward. Very good.

Well, thank you very much. The presentation is going to be fairly brief. It's just an update of what it is that the subcommittee is doing. The major focus -- let's see if I can get -- is the light the center thing? No. Is there a pointer on here? Yes, a pointer. Okay.

So, subcommittee charges and status. The first thing that we're going to be talking about is where we are with the review of the Department of Defense Centers for Deployment, Health, Research, and Clinical Centers. The paramount want that you've heard from the subcommittee about before -- you all know about -- is the Millennium Cohort Study. So, the question is, what are the three centers doing? Where are we with the review of these three centers?

The next question that we're going to talk about is to bring you up to date on the questions posed to our subcommittee by the inspector general. You remember that several years ago -- I think it was years ago, it seemed like it -- we did a review of the investigation conducted by CHPPM of chromate exposure at Quarmat Ali in Iraq, and I'll bring you up to date on where we are with the inspector general's questions to us about this investigation.

And the third thing I'd like to talk about today is the request for review coming from

the Assistant Secretary of Defense -- am I mangling that? That's true, Assistant Secretary of Defense -- about burn pit exposure in various places. But burn pit exposure to effluent coming off of the fires, whether it be diesel exhaust and micro fibers that are involved or the plastic and products of plastic combustion such as dioxin, et cetera, that may be coming off of burn pits.

So I'll bring you up to date on where we are on each of these three things. Before I do that I would like to at least acknowledge everybody who is on the subcommittee. The people without stars are people who were officially put on the committee. The people with stars are the ones that we kind of dragooned into service and are sort of unofficial members of the committee. And they've all played a great role, but that is the distinction between the stars and the non-stars.

So, in September 17, 2002 -- this is way back -- Dr. Winkenwerder, the Assistant Secretary of Defense, gave a -- made a request of the Armed

Forces Epidemiology Board. And that was for some group at the Armed Forces Epidemiology Board to meet with the three DoD Centers for Deployment Health, Research, and Clinical Center directors to receive mission briefs so we could find out what it is that they were doing. And then, secondly, to develop in coordination with the directors an appropriate strategy to accomplish an ongoing program review and appointment of an AFEB select subcommittee -- that's us, the Military Occupational/Environmental, Health, and Medical Service Committee -- to serve as a public health advisory Board to the DoD Research and Clinical Centers for Deployment Health, all right?

It's a lot of words, but I think that there were really two missions that we're supposed to accomplish. One is, go out and get smart about what the three centers are doing. And then three, try to play some role in an advisory capacity to the centers in an ongoing basis. So this is not a mission that's supposed to start and stop, we're supposed to have an ongoing relationship with the

centers.

This goes back to 202. Well, the review of the Deployment Health Research Center, which is in San Diego at the San Diego Naval Base was completed on May 11-12 of 2010. There was a subcommittee -- a report with recommendations which were presented at the West Point meeting at August 18-19, and were approved by the DHB core Board. Those recommendations have now been -- I'm definitely going to blow this -- they've been signed off by the Assistant Secretary's office, or acting in that stead, and are now going to be assigned back for implementation to --

MS. BADER: Back to FHP&R to review the recommendations.

DR. HALPERIN: To review the recommendations and implement as --

MS. BADER: And then develop a plan --

DR. HALPERIN: -- as they feel appropriate --

MS. BADER: Yes.

DR. HALPERIN: Okay. And if you

remember all some of those recommendations were -- if you will, the most general recommendation was for an advisory group for the Deployment Research Health Center in San Diego that would expedite reviews. There are now several review groups, the recommendation was for limiting it to one review group and having members of the Defense Health Board be active members of that review group.

So we've essentially completed, if you will, our mission at San Diego. Now it's time to move on to the review of the Deployment Health Clinical Center at Walter Reed and the Health Surveillance Center at Aberdeen, and that will be started, hopefully, in the next few weeks to months or so. And the way we'll do it is the same way that we did the first one, which is I'll go out with a staff member, try to get smart myself, if you will, reconnoiter or find out the big issues, and then bring the full subcommittee back in and do a thorough review.

It seemed to work effectively doing it this way for the first center. So, that's what

we're up to for the second and third centers.

Now, on -- just a little bit of background on Quarmat Ali for those people who don't know the substance or the details, which is probably pretty rare around this group. The site that we're talking about was contaminated with chromates. The chromates were used for rust prevention in water treatment. When soldiers, contractors, National Guard, regular soldiers got to the site there was contamination. It wasn't recognized for a while, once it was recognized there was a CHPPM field investigation, which resulted in interventions, along with interventions that were made by the contractor at the site. Anyway, this whole story was reviewed by our subcommittee, which we did under the strictures of it being confidential, secret information at that time.

We made a report, it went back through to the appropriate folks, and then there were subsequent questions about how we came to some of our conclusions, what we thought about a spectrum

of health issues, and so forth. We drafted a response, that response was reviewed by our subcommittee members, and was sent to the Inspector General -- I guess it was optional whether we wanted to participate or not. We decided to participate by providing that information, and it's been there since September 16 and I presume that this will rise again at some point. But at this point it's temporarily closed case.

On July 19 of 2010, there was a request from the Assistant Secretary of Defense office for us to review 2 things. One was -- oops -- one was a DoD report on -- it's actually not a report. It's a DoD proposal for future environmental sampling to be conducted at burn sites, burn pit sites, in the Middle East. It's really a research protocol, if you will. And the second is a report of an epidemiologic study that was done by DoD of health effects from prior exposure at other such sites in the Middle East.

And the teleconference was held on

September 10 to discuss ways in going ahead with this review. One of the issues involved was that our subcommittee, while very good, competent, excellent as you've seen from the list of people, really didn't have sufficient expertise in specific areas, such as exposure assessment, in monitoring techniques, and so forth.

So what we did is, we identified experts outside of our committee, mostly in academia. They were approached by Christine Bader. They -- apparently most of them if not all agreed to serve and now are waiting for further communication from the Assistant Secretary's office about how and when we can get going with one or both of these reviews. But we have agreed to do both of them. And that's where that stands.

This summarizes what I've already said, was that we had to augment the subcommittee in certain areas. And this lists those areas; epidemiology, clinical occupational medicine, and so forth.

And with that, I will stop and take some

questions and welcome Craig Postlewaite who arrived here. He may want to answer some of the questions as well.

DR. POLAND: Thanks for the update, Bill, on the activity of your subcommittee. Any comments or questions? Any of the Board members have?

Good. Okay. Thank you, Bill.

DR. HALPERIN: You're welcome, thank you very much. (Applause)

DR. POLAND: Good in uniform, there, Dr. Parkinson.

Our next two speakers are also members of -- illustrious members of the board are Dr. Michael Parkinson and Dr. Joseph Silva. Dr. Parkinson is past president of the American College of Preventive Medicine, and recently served as vice-chair of the American Board of Preventive Medicine and executive vice president, chief health and medical officer of Lumenos, a pioneer of consumer-driven health plans and a subsidiary of WellPoint.

A retired Air Force colonel, he formerly served as associate director of medical programs and resources in the Office of the SG. Dr. Parkinson also served as deputy director of Air Force medical operations and chief of preventive medicine. While assigned to the U.S. Public Health Service he provided oversight for federal programs and public health, geriatrics, and preventive medicine training.

He served on the National Advisory Committee of the Robert Wood Johnson Foundation Healthcare Purchasing Institute, assisting employers to purchase higher quality care. Dr. Parkinson is a recipient of the Air Force Legion of Merit, Distinguished Service Award of the American College of Preventive Medicine, and distinguished recent graduate award from the Johns Hopkins School of Public Health.

Dr. Silva currently serves as professor of internal medicine in the division of infections diseases and immunology at the University of California Davis School of Medicine. In addition

to his academic appointments, he served as consultant for Kaiser Permanente Hospital for the VA hospitals in Ann Arbor and Northern California, and is staff physician at the U.S. Air Force Medical Center at Lackland Air Force Base.

Among his numerous awards and honors are the Distinguished Physician Award from Sacramento Sierra Valley Medical Society, and from the California Hospital Association.

They're going to provide joint updates regarding the psychotropic medication and complimentary and alternative medicine. You'll hear them call it CAM work groups. And their presentation slides are under tab 7.

Gentlemen? The podium is yours.

DR. PARKINSON: Thank you, Dr. Poland. And good afternoon everyone.

As I said, Dr. Silva and I were asked by Dr. Lednar and Poland to chair this, although it relies very heavily on the expertise of Dr. Fogelman's committee. A number of the members in what we see as a kind of a cross-cutting effort of

major impact and importance to the Department, which is why it comes to us.

So, the question to the Board -- which I have actually asked Ms. Bader if at the end of our formal slides if we could just project the question or at least have it handy, because I think it's going to be critical to our work on Wednesday -- really has two parts. To request guidance for the prescribing and the proper use of psychiatric medications and, secondarily, to request guidance for the use of complementary and alternative medicine treatments.

And this is speaking to the use of these modalities for active duty members in the operational theater and perhaps throughout the entire continuum of care in the military health service. And really is the scope issue, which Dr. Silva will speak to in his comments.

The current membership which relies on some of our members of the board here you'll recognize, as well as some members external to the Board, has a good cross- section of folks who are

both active in the psychiatric and psychological health arena as well in the health care systems and care delivery arena, which I think is very important as well, particularly as the scope of this question begins to get into such things as benefits, civilian peacetime care, transition to the VA system, et cetera.

We had an organizational teleconference on the 21 October. This was just a grounding effort, I think. It was very valuable for us to discuss some of the impending issues, which Dr. Silva will review in his comments. But really just to meet some people, telephonically, at least, for the first time in an abbreviated but very useful kind of a foundational effort. Our first meeting is this Wednesday. We will use that to acquire a lot of information about the background of the question so that we can be informed on the topics. And as Ms. Bader mentioned, the final report and recommendations -- it's relatively tight timeline for something that could be as broad as what we perceive in the

question. So, that's why scope is all the more important. Either the scope is different than what, at least, I read, or the timeline has to be significantly extended. We can't put a size 9 foot into a size 6 shoe.

So, on November 3 we want to talk about the scope and priority areas. We will discuss with the service psychiatrists exactly their perceptions of these two areas and their role in it. We will have a review by the mental health advisory team on the data of medication use, psychotropic drugs, in theater. What are the data sources we can rely on to find the prevalence of use of these drugs in theater. And also at a high level, the evidence base for the use of medications for PTSD and acute stress disorder.

Joe, is this your slide? Am I in your area?

DR. SILVA: No, that's yours.

DR. PARKINSON: These are mine, okay. Because some of these I know nothing about. I'm just kidding.

No, this was an area, I think, that frankly reflected some of my meandering comments, probably, on the telephone conference call on our last. Is that certainly a case definition of what is and is not "CAM" and what is it's use in the Department of Defense on the continuum of mind/body issues. We have military facilities where we actively promote GNC stores. Not picking on GNC, they're based in my hometown of Pittsburgh, but there's a lot of things in those types of outlets and in the types of advertisements that float around military bases that could broadly be considered CAM. Are those embraced? Are they not? Either in policy or in treatment with our troops.

We need to know something about the capability of in-theater psychiatric care, certainly about the baseline prevalence of the use of these medications. There's been a tremendous amount of literature about the widespread use of psychotropic medications in the general civilian population. I, myself, have not seen a single

employer where it's not the leading category of drugs that are prescribed for employees and their families, for example.

And then, we want to break out into work groups based on what we learn in the morning, in the afternoon, to use our expertise to formulate a plan going forward.

Still mine?

DR. SILVA: You can take it.

DR. PARKINSON: Okay. (Laughter)

DR. SILVA: We're well-rehearsed.

DR. PARKINSON: This is the Alphonse-Gaston. I got it, you take it. Okay.

The scope of interest is very important, particularly are we talking just about in theater or are we talking about transition out of theater, or are we talking about transition to the TRICARE benefit? So if you go back and review the question, what is written in the question then refers to the attachments. The attachments really have words like "the benefit." Benefit determination is very different than in-theater

treatment or something using psychotropic medications and CAM.

What are the definitions for psychotropic medications and CAM? Do we have uniform utilization of the terms across the services and within the Department vis-`- vis civilian practice? And what is the availability of these various treatment modalities within the military, generally within the TRICARE benefit, within the theater operation?

And certainly we're into the -- immediately into the bailiwick of what are FDA-approved versus non-approved uses for these various substances. And certainly, even so much as to what does the NIH, the complement and alternative medicine branch, have to say about the framework for the definition of these issues as well as a way to think of them from an evidence base, realizing that by definition many of them do not meet the evidence base that clinically we would think would be appropriate.

Dr. Silva?

DR. SILVA: I want to thank my ex-friends, Drs. Poland and Lednar, for putting me on this committee. (Laughter) On the telephone call I sort of had a feeling when I was a young kid of scratching on a bees' nest, and I heard a lot of noise underneath. And so that's how I viewed this problem, and how do we get our hands around it. And I think it's a very important problem.

If one goes to the font of all current human knowledge, Wikipedia, which I've done, just to look how many drugs are in each of these categories, it's astounding. There's over 80 on the psychotropic side. But if you punch in other terms such as psychiatric or psychoactive or psychopharmaceutical, you can get different types of drugs. And then the CAM list, I sent you -- I didn't even count it up, Mike, but I think you have a bigger chore. So that's a real problem, defining in theater and what are we talking about.

Now, if one looks at where the problems are coming from I think there's no doubt that this

is a perfect storm. There are really two elements, like the movie. Wind and rain. And when you come down to this, we're really talking about the items of patient expectation. There's a huge industry out there built over these products, word of mouth. And when people are stressed, they are going to demand things.

The other side are the pharmaceutical industry themselves, including those that make CAM. And I think there's going to be a real, real problem. We've already started to pull out some data as to what are some of the psychotropics that have inappropriate use physicians in terms of pushing their drug outside the limits by approval from FDA. And I'm going to give it to the committee; we've already sent it on.

There's an interesting court case that came out of this nonprofit -- I'm sorry, ProPublica. It's a nonprofit organization which many of the drug houses use to funnel dollars through to physicians. And we're not talking about small amounts of change here. I was amazed

at what the problem was. But if you look at the data, there are about eight companies -- I won't read them. Dupont's not there, Mike, so you can relax.

They had 384 physicians received over $100,000 a year since 2009. They had 2 in the last -- I'm sorry, they had 43 in the last 2 years who have received over $200,000. And then there are two people driving a Lexus who had over $300,000 a year.

And there's no doubt the companies have been at this for ages. They have a lot of schema how to push the drugs in the limit. And so, they use it out of approved drug use. And in fact, there are estimates now that about 20 percent of all drug use offline is a common figure that's quoted. So, this is a huge industry. Besides the fires and the TV ads, ask your doctor, the effects of a lecture getting to health care providers -- there's still a very, very powerful force and it does push physicians and healthcare providers to try to experiment with drugs.

So, the tasks are pretty bold. But I think we can get a handle on it, because one that clearly we can address on what are the current uses, and some of these people legitimately need to be on these agents when they go into theater, they are useful. I was amazed to find out that during World War II over 60 million doses of amphetamine were uses on the Allied troops' side. And also I found a reference in Sierra Leone when they had the children warriors that it was common they got mixtures of gunpowder, cocaine, and amphetamine. So there are mind altering drugs that are used to sort of jazz up the troops.

The other thing, I don't know if we can get a handle on but there are side effects to these agents that we hardly ever talk about unless they're really bad. We may get some inkling at that if we can data mine some of the pharmacy banks as to what side effects have been after return from theater.

But with that, I'd like to open it up and have Mike field some of the questions, because

my codeine is wearing off and I'm in pain.

Anyhow, we're open to your thoughts. We're going to go into this naove and hopefully be able to carve out a product that will be worthy of this Board to approve. So.

DR. POLAND: Thank you guys for your report there. And we have time for any questions, comments, any directive ideas anybody has, whatever it would be.

DR. SILVA: And, Charlie, we're going to be heavily dependent on your committee to react here, too. That's obvious. So.

DR. POLAND: Dr. Luepker.

DR. LUEPKER: Yeah, Russell Luepker. So, presumably active duty people are receiving these medications by prescription through normal channels. And presumably that's findable. But all the CAM medicines, how would you learn about that? Usually off the supermarket shelf or at General Nutrition.

DR. PARKINSON: Well, Russ, that's an interesting question. Because if you had to do a

similar study in the civilian there's any number of traditional epidemiologic tools that we can do. You could do surveys, you could basically do purchasing by geographic areas, you could do -- but it's relatively crude. And to go back to the first and foremost question is, what's in scope for this particular -- this topic?

I, for one, would like to have a very discrete, defined typology for what is CAM. It is probiotics, it is vitamins and supplements, it is hypnosis, it is -- you know, zing, zing, zing, zing, zing. And, hopefully, we don't have to make that up, it's out there. And that's kind of what my education is going to be. Charlie, maybe you want to comment here.

But I think that within that we then have to ask the question, are we talking -- I think our first and foremost goal is about operational performance in theater. And that is both operational performance, is it just to maintain current operational performance? Or is it to actually, as Joe alluded to, to enhance

operational performance? Go/no go pills, as they were called in the Air Force. That was a standard treatment that we did for long missions in Vietnam. So, is that in scope? Are we talking about performance-enhancing operational psychotropic medications? Or are we talking about just operational deleterious drugs?

Again, those are the things that we'll work through. But I do want to mention a thought that I had this morning for the group, putting on my role as a Board member. When I listened to Dr. Jim Kelly's presentation about the Intrepid Center, if you look at the mission -- and I tagged it in my book -- but you go back and you look at the mission slide at the Intrepid Center, actually there's about an 85 percent mission overlap with the question that we've been asked by the DHB. Individualized, multi-factorial treatment plans for individuals to be able to optimally function. This is active duty members, so one of the recommendations over lunch that I had to Christine is perhaps we want to ask and suggest that if Dr.

Kelly would like to be a member of our group, because he actually has to apply in a very real time to people who have been in theater to make the more operationally function with a combination of TBI and psychological stressors. So, it might be something to think about to knit together our efforts a little more closely.

Just for your information, there was the original question but then there is about a page and a half of all of these questions that, as the Board will recall, are appended to the question itself. Which is where each one of these questions gets successively broader and broader and broader, if you will, in mission creep or scope creep that both Joe and I feel, while interesting, probably is not achievable by March 31. So that's what we need to do is to find how deep and how broad do we need to go.

DR. SILVA: Let me just add to the CAM area. Russ, I think your question is good. And of course the troops receive packages all the time from people. So if it's not available in the

local market -- although a lot of stimulatory agents out there, packaged in a lot of unique ways worldwide, then they can get their families to send it.

And if you go into these 7-Eleven stores, you're getting gasoline, look at what are big sellers now to teenagers, young drivers. I just discovered this when I ran across a couple of these products in psychotropics. They're loaded with caffeine. They're called power drinks, they're chewing gum. You can take five- and six-hour doses of incredible amounts of caffeine to remain awake. And I bought a pack of the gum. It was very expensive, $3.43, which --

DR. PARKINSON: But you're awake --

DR. SILVA: But I'm awake now. (Laughter) And I'll tell you, you could really get jazzed up. When I used to be a coffee drinker, 8, 10 cups a day, I think one of these things has the equivalent, easily, to 3 or 4 cups of coffee drank over an hour or so.

Anyhow, it's pandemic out there.

DR. POLAND: We'll be putting it out instead of snacks for the board. (Laughter)

DR. PARKINSON: Well, if you could just -- and again, just step back for a minute. And you could turn an entire -- at least a supplement to the American Journal of Medicine or, you know, for number 2 and number 3, two separate supplements to talk about what is the evidence, the real, perceived, or extrapolated evidence for the treating of some of the most common anxiety stress disorder. I mean, so, again, this is so broad in the attachment that that's why we really rely on the Department for guidance here.

DR. POLAND: Okay, thank you very much. (Applause) We're going to do a little more agenda shuffling here. We're going to take about a 20-minute break and then we're going to ask Colonel Hachey to do his brief on H1N1 look-back, which is scheduled for tomorrow. This will allow two things. Time for PT today, and time for PT tomorrow.

Dr. Butler previously worked with the

Navy SEALs, he'll be leading the core board in this endeavor.

(Laughter)

(Recess)

DR. POLAND: Can we have folks take their seats? We'll get started, because I know you'll want to do your run while the sun is still out.

Okay. Our next speaker is Colonel Wayne Hachey. He currently serves as the director of preventive medicine and surveillance in the Office of the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness. He has a background in both nursing and medicine. During his nursing career, Colonel Hachey held faculty appointments at the University of Nebraska and East Carolina University. He also held administrative and clinical positions as a director of a nurse practitioner program and as a neonatal clinical nurse specialist nurse practitioner.

Prior to transitioning into medicine,

Colonel Hachey served as a clinical nurse specialist in the U.S. Army at the Walter Reed Army Medical Center.

We've asked him to do sort of a look-back on the accomplishments and critical lessons learned regarding Department of Defense H1N1. It's under tab 10. Like me, I'm sure you'll find that almost nothing else is as fascinating as pandemics. (Laughter)

COL HACHEY: A second only to seasonal flu, yes. Well, it's been said that no plan survives their first contact with the enemy. But despite that, DoD didn't do too bad as far as our planning and the H1N1 pandemic. We did start our engagement that actually predated the national strategy for pandemic influenza, so DoD was always a step ahead. And then we partnered with the National Pandemic Influenza Plan in with other federal governments and agencies. And because of that groundwork, I think we were in a much better position.

When the pandemic actually hit we were

able to meet our mission requirements while operating in a pandemic environment without mission degradation. And we adapted to changes in the disease characteristics with changes in our resources and changing in planning.

Well, if any of you follow NPR, it's time for the numbers. So, the number of beneficiaries seeking care for flu-related symptoms was actually four times higher than what we saw in the typical flu season. So it did have an impact on DoD. Ambulatory visits were up five times -- actually, a little more than five times. And the direct care system -- and threefold in the purchased care system. ER visits were up fivefold in the direct care system and eightfold in the purchased care. And inpatient admits were up 5 times in the direct care versus 2.8 in the purchased care sector.

So across the board, whether you were in a direct care metric or a purchased care metric, utilization was up across DoD. And the overall cost was, let's see, $156.7 million above a

typical seasonal flu, with 71 percent of that cost going towards active duty and dependents, which is a little bit of a flip-flop. Where in most seasons the folks were being hospitalized and running up your bill are those who are over 65.

As far as DoD deaths, we had two active duty deaths, six family members, and three retirees, which is not unlike a typical seasonal flu. During the past six years, our seasonal flue rates for deaths range from one to two. So, this is clearly within the bounds of, again, a typical season.

However, just like one suicide in DoD is too many, one death from influenza is also too many. And this is one of our DoD deaths. On October 30, 2009, this was a previously healthy 7-year old. On the third day of a flu- like illness he developed worsening symptoms and was brought to one of the region's premier military medical treatment facilities and was diagnose with croup. The next morning he was better, but by the afternoon he was walking unsteadily and was found

to be cyanotic and rushed to the nearest ER. He was pronounced dead two hours later, and was later diagnosed with 2009 H1N1.

So, what did we do as far as planning for the pandemic? Well, DoD combatant command, service, and installation plans were all in place before the emergence of the novel flu strain. The problem is that they were primarily based on an H5N1 threat and not on an H1N1 threat, which turned out to be very different.

There was some initial confusion between WHO phases and U.S. government phases. Many of the combatant command pandemic influenza plans were based on U.S. Government stages rather than WHO phases. That confusion was exacerbated when the federal government elected to follow the World Health Organization's pandemic flu phases rather than the U.S. Government phases. With many of the combatant command triggers, again, based on the U.S. Government phases. So there were many folks, at least outside of the medical arena, were left waiting for that trigger to happen before

they initiated some of their plans. However, the medical community quickly adapted from a bird flu threat to a 2009 H1N1 threat.

Another problem we found is that the policies were primarily focused on uniformed personnel. So for anybody in uniform, we pretty much had you covered. However, there was limited inclusion of civilian personnel in most of the DoD policies. The civilian personnel office, however, quickly issued guidance to meet identified gaps. But there was a period of time in-between the time that the gaps were realized and the time that the guidance went out, where there was some confusion on the ranks of our civilian personnel.

Another problem was, we all said, okay, you have to identify who is essential. Because if we have a shortage of vaccines or if the disease severity increases we want to know who need to give, let's say, antivirals to. And some folks were able to pare down what essential actually was. Other people had more difficulty doing that. Where some combatant commands felt that everybody

in their command was essential, to include the folks who were giving you your eggs in the morning to the missileers with their fingers on the launch buttons. So, that did lead to some difficulty as far as paring down limited resources, if we had had to go to that extent. Nonetheless, plans and policies were quickly modified to meet the new requirements.

Workplace policies. DoD was able to leverage the Office of Personnel Management and OSHA guidelines, aid in implanting work first protection policies. However, there was no uniform policy regarding civilian employee absentee monitoring or reporting. And one of the reasons why that was a problem is primarily HIPAA. That we weren't able to force employees to tell us why they were absent. So even though that was a gap as far as our ability to ascertain why folks were absent or what the impact was on our civilian workforce, our hands were pretty much tied due to regulations outside of DoD.

A few years ago we had an exercise to

see if we could do teleworking, and on a small scale it looked pretty good. However on a larger scale we found that we didn't have enough laptops to go around to implement wide scale telework getting to -- to facilitate social distancing.

Shifting gears to surveillance. The DoD surveillance system was really a key component in the initial recognition of the pandemic, and ongoing surveillance efforts. If you look at where the surveillance eyeglass was set for most of the folks in the U.S., they were all looking towards Southeast Asia. And that's where the bulk of the surveillance was.

However, DoD was looking both offshore and inward. And it's because DoD had that 360 view that DoD surveillance activities were actually responsible for picking up the first four cases of the H1N1 strain here in the U.S. And that represented three different components of our influenza surveillance program.

As soon as we realized that something was different out there, the DoD surveillance and

public health community were put essentially on alert to look for further cases, particularly on those installations that were along borders with Mexico.

And then our surveillance assets were able to continue to provide timely information to DoD leadership. However at times, the frequency of the data calls, at least by some perspectives, seemed to be somewhat excessive at times. DoD leadership had a rather large need to have the latest numbers on pretty much a real time basis, which led to some problems with reporting by our surveillance community.

Nonetheless, the Armed Forces Health Surveillance Center fostered a communication network between our laboratory and public health community, along with Health Affairs to identify key issues and quickly adapt policies to meet ongoing requirements.

Another issue was our laboratory assets. When the pandemic first started it was only the state public health labs and two DoD labs that had

the FDA-approved diagnostic platforms. And that was primarily due to the CDC's choice of which platform they were going to request FDA approval for.

Shortly thereafter the FDA, through an emergency use authorization act, approved the ABI 7500 fast platform, which we had a lot more of. So the result was that, for example, that USAFSAM -- the Air Force increased their typical annual capacity of about 5,000 samples per season to 23 samples. And with that emergency use authorization, then there were ample diagnostic platforms across DoD, and for that matter across the civilian sector.

Initially our sampling was targeted towards confirmation of disease in local populations. And then later after we established, yeah, it's here, it's in all our communities, then what we wanted to do is just confirm disease in hospitalized and high-risk populations. However, the labs did experience an increased workload, primarily because of the line still needing to

have that data as far as exactly how many cases they had in their population, despite medical guidance for more targeted testing.

Also, there was a number of requests for assistance to the states. And at first we were unable to provide that because our hands were pretty full, which is DoD testing. And later, we weren't able to provide as much assistance to the states as they would have liked because of their reluctance to enact the Economy Act or the Stafford Act, which would have permitted DoD assistance and also payment for our assistance.

Shifting gears, antivirals. Oseltamivir represented the bulk of the DoD stockpile, and that was primarily because we were planning against an H5N1 threat. We had 8 million treatment courses, 1 million at our medical treatment facilities, and that was under local use and use authority; and then 7 million additional treatment courses in 3 strategic depots, 1 in the Philadelphia area, 1 in the Pacific, and 1 in Europe. And our antiviral policy mirrored the

CDC's with the exception of expanded use to maintain operational capability.

So the policy was first medical discretion for use. Very limited outbreak prophylaxis, by all means provide antivirals for all those hospitalized with confirmed or suspected disease. Provide antivirals to all those with high risk conditions who have suspected or confirmed disease or suspected or confirmed exposure. But if you weren't in a high risk population group and you had mild symptoms, then our guidance was that you didn't necessarily need to provide antivirals. The only exception would be if operational requirements mandated treatment based on mission and not necessarily medical risk.

This chart just gives you an idea of what our antiviral use was. The kind of melon color is outpatient use. The blue is inpatient use. And just like the epi curve that we saw with the pandemic and you can see that we had a fair amount of antiviral use. And this is primarily all oseltamivir.

However, there was very limited use of the antivirals that we purchased for our pandemic flu stockpiles. Most of the antivirals that were used were the higher priced antivirals. Same antiviral, just we paid four times as much for it. And there was a -- for some reason there was a reluctance by many of the services to approve the release of the antivirals that we had provided for them for more tactical use.

So, our stockpile went largely unused, despite a number of pleas to please use the cheap stuff and please use the stuff that we've stockpiled for pandemic use.

The way ahead for antivirals? Again, our antiviral stockpile was predominantly oseltamivir. And again, that was based on the H5N1 threat. Since then we've received supplemental funding to replace the few doses of oseltamivir that we, in fact, did use from the stockpile. We're also adding rimantadine to the stockpile to at least permit multi-drug therapy. We're also increasing zanamivir, both locally and

in our strategic stockpile so that zanamivir will represent about 30 percent of our overall antiviral stockpile. We also have funding flexibility that would permit the addition of new antivirals if they become available.

Probably the greatest source of angst across DoD was related to vaccines. And actually I had just gotten security clearance for giving this about 20 minutes before I started, and they requested that we delete this picture. So, please enjoy it before it goes away. (Laughter)

But vaccines were pretty much the bane of everybody's existence. Both the immunizer and the folks over at Health Affairs and the services. Part of the problem is that first we didn't know how much we were getting. They were shifting vaccine projection at least as far as our operationally-based vaccine. So, up until May of 2009, we were all under the assumption that we'd be following under the National Vaccine Allocation Prioritization Plan. In which case, DoD was supposed to get 700,000 doses right off the top,

first vaccine off the production line. And then after other high priority groups were filled, we were supposed to get 650,000 doses. And then a little later on, 1.5 million doses.

Plan presumed that, again, we were dealing with an H5N1 threat. However, once the 2009 H1N1 turned out to be a little less severe that what we were thinking of as far as a bird flu threat, the U.S. government abandoned this plan and shifted to a different plan.

Which led us to June of 2009. And at that point, DoD agreed to purchase 2.7 million doses with 1 million doses delivered early-October, followed by 1.7 million doses no later than -- they said late-October, maybe beginning of November. So, by the first week in November, we were sure that we would have our full 2.7 million doses and we planned accordingly.

Then, in September 2009, we were notified that while vaccine projections were maybe a little higher than what was anticipated, and that we'd be getting vaccine at a slightly lower

rate. We began to receive vaccine in late-October. Vaccine delivery notification usually happened about 24 to 48 hours before we actually had it in hand. So as far as projecting when we were going to be getting vaccine and where it was going to be going became somewhat problematic. And we completed our 2.7 million doses, actually, on Christmas Day. So, a bit different from what our initial projections were.

The other problem is that we bought vaccine but we really didn't own the vaccine, that HHS controlled all vaccine allocations. And there were three different programs that DoD participated in. These were not by choice.

So, the first was our operational vaccine, and that's the 2.7 million doses. And you can see that we got that a little slower than what we had initially planned. And our order was completed a bit later than what we had initially planned. However, the allocation was controlled by HHS.

Another program that -- on that targeted

primarily uniformed personnel, health care workers, and some DoD civilians. The other program that we dealt with was the state allocation program. And this was the same program that everybody in the rest of the country dealt with. So each state was given a per capita amount of vaccine to be distributed among their population. So, the installations enrolled as immunizers. So, Walter Reed just like Georgetown and GW and the Mayo Clinic all had to say, yes, we are going to provide vaccine. And then they were given vaccine based on their population. And this could only be used for healthcare workers and our dependent population.

The third program that DoD participated in was the federal employee program. And this was targeting U.S. Government employees. And it turned out that when they totaled up all the numbers, DoD has about a third of all the U.S. Government civilian employees. So we were asked to use our distribution system to get vaccine out for that population group.

Now up until then, HHS had refused to supply vaccine for our OCONUS dependents. With our participation in this program, the agreement was that we would be getting extra vaccine through the federal employee program for use for our overseas dependents. So they wound up being covered that way.

So, we had three different programs, three different rules of engagement, three different populations that those vaccines could be used by, which created a fair amount of confusion at the local level.

So, switching back to our operational vaccine. Our vaccine prioritization. First to receive that operational vaccine were deployed and deploying forces. So, the folks that got vaccine first were USCENTCOM and U.S. forces Korea. Also, our health care workers, large training venues, and ships afloat.

So, that targeted the folks that we felt were at highest risk for disease transmission. The problem was that when you send your first

aliquot of vaccine to deployed people, then that meant that active duty members at OCONUS installations would be getting their vaccine much later. That in the face of their dependence getting vaccine much earlier through the state allocation program left two different populations, the uniformed people that did not have access to vaccine, and the dependents that did. So, somewhat of a switch from what oftentimes happens during seasonal flu seasons.

The other problem was that, again, USCENTCOM and U.S. forces Korea received the first aliquots of vaccine that DoD was given. U.S. forces Korea pretty much immunized most of their people almost nanoseconds after it hit their shores, maybe a couple of days. But USCENTCOM, it wasn't until December that they were able to actually get all of the vaccine that they got upfront into arms. So that delay in actually getting vaccine into service members diverted some vaccine that we could have sent here OCONUS.

Another problem was that the -- we left

it up to the services to define who was deploying and, again, who critical personnel were. And those definitions varied from service to service. So, there were some inequities as far as the amount of vaccine that went out to the services, particularly when we were targeting the deploying forces.

The other problem was that everybody wanted vaccine. So, when we queried the services in OCONUS with their -- what their entire vaccine request was, it actually exceeded our end strength. So, the number of folks that they said needed to get vaccine actually exceeded the number of folks that they actually had, which also led to some problems as far as distribution.

Another issue as far as vaccine? There's about a three week delay by the time that DoD received vaccine that you can see in the kind of pink boxes, and the times that it actually got into arms. And there's a number of reasons for that.

One reason is that vaccine stayed in the

depot for one to two weeks after we received it. The depot worked on a five-day workweek with a time off for holidays. So, that led to some delays. Had it been a more severe pandemic we hope that they would have adopted a 24/7 workweek. The other problem is that the depot could only get -- it was about 100,000 doses a week, just as far as capacity and throughput, which led to another delay.

The -- let's see. I already said that. The last thing is that as vaccine trickled down to the MTFs, the desire for vaccine was kind of waning a bit. So, command emphasis probably was not quite as stringent as it would have been earlier in the pandemic when the disease threat was higher.

And despite that, regardless of how quickly or how slowly we had gotten vaccine, it didn't seem to impact on our epi curve. Again, the red bars here are outpatient visits, the blue hospitalized visits for ILI rates across DoD. The percentages are when we saw vaccine.

So you can see that the epi curve was already really plummeting by the time we started receiving any appreciable amount of vaccine. So, the impact we had on the pandemic as far as maintaining operational effectiveness was primarily due to all of the other stuff that we had in our plans as far as social distancing, antiviral use, close surveillance, and probably not vaccine.

The -- again, the other program that we had was the vaccine for dependents. We already mentioned that each installation received a prorated amount through HHS allocations for dependents, healthcare workers, and retirees. And DoD policy made this vaccine available for active duty members if they had a high-risk medical condition. We felt that if we had a pregnant active duty mom out there that, yeah, even though we didn't have the right color vaccine if we had vaccine on the shelf we wanted to make sure that they were protected.

But again, the end result was vaccine

was available for dependents before it was ready for or available for active duty members. And the HHS rules of engagement prohibited cross-use of vaccine.

Now, some states -- one in particular. Actually, Minnesota noticed that, you know, there's this disconnect. That your active duty members don't have vaccine and your dependents do. And they approached a number of medical treatment facilities and said, would you like a little extra? At which we said, sure. So, in some instances the states recognized that there was a disconnect there and did come to DoD's rescue.

Other states, however, were less friendly and didn't want to give us any vaccine. I won't mention which one -- New Jersey. (Laughter) But nonetheless, it was kind of yin and yang as far as the states treated DoD.

Another problem was that to provide vaccine for your dependents and retirees, again, you had to register as an immunizer. If you were one of the unlucky installations that serviced a

number of states, you had to register with each one of those states and each state had different reporting requirements. So, it left a number of the installations feeling a bit schizophrenic in dealing with a number of states as far as getting vaccine for their dependents and retirees. And like the Sudun community, vaccine supply came long after the peak in demand.

And one other thing about this is that we were never really able to capture what our vaccination rates for our dependents were. There's only one service that does that well, and unfortunately it's the Air Force, not the Army. And the other services, their immunization tracking systems do not capture dependents. So knowing what's happening in the DoD community was somewhat lacking. We had a good handle as far as who in uniform was immunized but, again, not our dependents.

And actually I already mentioned this, just the U.S. Government civilian employee program. And again, by the time vaccine was

available, then the demand had dropped off.

One bright note is that one of the deals as far as DoD getting vaccine is that we would provide vaccine to the Department of State and the U.S. Coast Guard. The Coast Guard because they're a uniformed service but they're not part of DoD. They're a kind of like an orphan child where the Department of Homeland Security owns the Coast Guard but they thought DoD was going to supply them vaccine, and DoD thought that Homeland Security was going to be supplying them vaccine. So they were kind of left somewhat in a lurch.

So, the Coast Guard was supplied a vaccine from our operational stockpile. Vaccine to the State Department, however, was delayed due to regulatory requirements. Shakespeare was right as far as what we should be doing with lawyers, and because the vaccine was purchased in the prior fiscal year, we couldn't transfer it to another U.S. Government agency because we couldn't be paid for it with the next fiscal year's dollars.

SPEAKER: What a country.

COL HACHEY: So, that led to some delays. But each one, the Coast Guard and the Department of State, got 50,000 doses.

Again, vaccine tracking. Each service has its own vaccine tracking system. With, unfortunately, less than optimal integration of the three tracking systems as far as an overall DoD picture. And again, only the Air Force effectively captures dependents and retirees.

Also, the use of non-electronic immunization administration records resulted in some delays in entry with an unknown degree of lost data across the system. Another problem was that the reservists and National Guardsmen could receive vaccine from civilian sources. And transcription of their immunization status to DoD databases had variable compliance.

Despite that, we did reasonably well. And this is as of March 30th. Colonel Krukar had sent me an e-mail just before this that our numbers actually look a little better after a few months have passed. But if you look at the active

duty forces, we're all pretty much close to 90 percent. And again, these numbers all have gone up since this last report.

So overall, DoD was fairly effective as far as getting vaccine either into arms or into noses, depending on the vaccine type.

Communication. A use of the H1N1 watch board and the MILVAX Web portal were effective communication tools to inform commanders, service members, DoD stakeholders, and beneficiaries. One example is DoD pandemic flu watch board that we briefed the board on previously had 8 million hits between April and January. And MILVAX website was averaging about 35,000 hits per day. So, our -- at least our websites were a well-known before the pandemic started and used fairly effectively.

Another thing that we used was some flash messaging services that targeted our pharmacists. If we needed to get word out today so that each medical treatment facility, their providers knew by close to business day, we used, again, MILVAX, their communication network to the

pharmacists who then relayed it to their providers.

Some installations also had call centers. But communication was variable at local levels as far as regarding vaccine availability, particularly in large metropolitan areas where some of the dependents had some confusion -- for that matter, the installations had some confusion as far as what was available in their local areas.

So, what are some things that we can fix? Well first of all, funding. Supplemental funding was received for the purchase of antiviral medications. So, again, we're putting that towards a replacement of oseltamivir stocks, buying more zanamivir or Relenza. Also, some rimantadine. And again, if the next best thing to white bread comes out as far as a new antiviral, we'll have the ability to purchase that.

Another thing that we've received supplemental funding for is more personal protective equipment for use by our healthcare workers. And that's replaced existing stockpiles

and to actually increase stockpile levels.

A third component in supplemental funding was to also increase our surveillance capability. On a year-to- year basis we've requested POM funding for enhanced surveillance. The maintenance of our existing stockpiles -- once it costs money for storage and stability testing. And then, ongoing antiviral and vaccine acquisition. However, that overall program is in jeopardy if that funding is not received. And that is still being reviewed.

More stuff that we can fix. You know, one thing that we did learn is that as a department we need to be a lot more proactive as far as making sure that vaccine purchased by us is owned by us, then used when and where we want to use it. So that we're not, essentially, held hostage by another U.S. Government agency who, in all fairness, had a bigger piece of the pie to provide vaccine for. We're also expanding our antiviral portfolio. And one thing that's going to be fielded, at least in a pilot form shortly,

is a uniform immunization tracking system where all three services will be using the same system, so we will be able to have a good idea of what our immunization rates are across the DoD spectrum.

And another thing that is new is that using the DoD pandemic influenza plan. DoD plans are now being adjusted, not to center just on pandemic influenza, but to encompass all biothreats. So, we have more of a flexible response to a wide array of threats.

So, one thing we've learned during the past pandemic. You know, it really does matter what you buy. You know, give you a second to -- and this, too, will be the last time you see it, because it was pulled by our security folks. So, enjoy. (Laughter)

So, as far as response options. You know, the choice is ours. We can take either approach and with, essentially, ongoing funding and the lessons that we've learned from this past pandemic, we got off fairly easily once there was a relatively mild severity. But if the next one

is more like an H5N1 threat, then hopefully we'll be the duck with his head above water.

And any questions? (Applause)

DR. POLAND: Comments or questions? Frank?

DR. ENNIS: Thank you, Colonel Hachey. It -- we've talked about this before, this committee. But -- and probably the blame resides with HHS. But, in fact, it was a failure. All the vaccine was given after the outbreak. So, although a lot of people were immunized, it wasn't given at the appropriate time.

And I think forbearers on this committee would roll over in their graves if they knew the DoD lost control of the ability to immunize against influenza in a timely fashion. The decision was made high up. But I don't think DoD, you know, was effective in immunizing the troops last year.

DR. POLAND: Joe.

DR. PARISI: Thank you very much for the presentation.

I had a question about the tracking system that you're developing. Do you have a time frame for that? I mean, it seems like that would be a very -- a much more efficient way of ensuring that the troops are immunized at the appropriate time.

COL HACHEY: Let's see. Colonel Krukar can correct me -- or actually, I'll just let him speak.

COL KRUKAR: That universal immunization tracking system is being established, and still some requirements are still ongoing for this. But it's going to be given back over to DHIMS to begin implementation, and the plan is for March of next year. And then with the full rollout to the MTFs beginning 1 October of next year.

So we're still about a year away from this.

DR. POLAND: Bill?

DR. HALPERIN: Bill Halperin. Do you foresee in the future being able to do vaccine effectiveness in real time with some of the

systems you're developing?

COL HACHEY: Actually, that's a good question. We -- probably not real time, but as the pandemic progressed through the -- actually through the Armed Forces Health Surveillance Center we were able to get kind of an ongoing tally of how things were looking.

But unfortunately, you need, you know, fairly substantial numbers to get some reliable data. And particularly the way we got vaccine, you know, it kind of trickled on in. So, the other problem was disease ascertainment. It was some problematic, at least last time. So, if we have like an H5N1 threat where, you know, you know you have disease because you're dead, then I think things might be a little easier as far as getting answers like that. But with the -- at least with the past pandemic, once we weren't quite sure how many cases were unreported, especially early on, that would be a problem.

DR. HALPERIN: The disease ascertainment I understand as a problem. But I didn't actually

understand the comment about the OSHA regs because I didn't think that federal employees were covered by OSHA.

So, if the DoD wants to know why somebody's out?

COL HACHEY: Oh, that was not OSHA. That's -- actually it's HIPAA --

DR. HALPERIN: HIPAA?

COL HACHEY: And that governs the civilian workforce. So, for our active duty force, yeah, we own them. But for our civilian workforce we still have to follow HIPAA regulations. And for that matter, for our uniformed folks, the same thing applies.

DR. WALKER: So this pandemic flu didn't occur at the same seasonal time that the flu epidemic does? Is there any way to prepare for that happening?

COL HACHEY: Actually, I think we were -- as far as DoD, I think we were well prepared. You know, again if it wasn't for the DoD influenza surveillance system working year-round, that we

wouldn't have picked up those cases. And our plans were in place, our stockpiles were in place. So it was just a matter of essentially pulling the trigger and saying, it's here.

So, at least from our perspective, the seasonality was less of an issue. Except for the vaccine production.

DR. SILVA: Joe Silva. Thank you for tonight's presentation, again, Wayne.

Those deaths that occurred. Were they analyzed for receipt of vaccine? Did they get Tamiflu on the ride down towards death or any other antibiotics? Had they been dissected yet?

COL HACHEY: Let's see. I only know of a couple of them. I don't know all eight. But the one that we presented today did not receive antivirals. I believe at least one of the active duty members had not received antivirals. And actually let me take that back -- one additional dependent also didn't receive antivirals. And the lion's share of the folks were pre-vaccine, if not all.

DR. LEDNAR: Wayne Lednar. Colonel Hachey, you mention on your next to last slide that going forward the DoD is planning on adjusting its approach to encompass all biothreats. So my question is, how will you do that? What will be the data sources that you'll sort of keep your finger on the pulse of what these threats are and where they are? And then, have you thought at all about how you'll prioritize those threats?

COL HACHEY: Well, as far as knowing what's out there and what's happening, that would be just our surveillance system that's already tracking all of those threats anyway. So, there's no shift there.

As far as the prioritization of the threats, that may become a problem. And the reason for that is funding. That I'd say the threats that are more tailored towards intentional releases may receive more funding than those that are released by Mother Nature. So, there is that potential of prioritization based on funding

rather than on the threat to the force.

So that is an issue that we do need to look out for.

DR. POLAND: Dr. Shamoo?

DR. SHAMOO: Adil Shamoo. I guess now we laugh about these hiccups. But our job is to help them in prevention and treatment. And this vaccine was a prevention.

If H1N1 was as virulent as everybody thought of, each one of these hiccups could have cost us tens of thousands of lives and there would have been a big scandal. And I'm thinking, what can we do to help mitigate those barriers ahead of time rather than wait for another epidemic -- or potential epidemic.

DR. POLAND: Just to correct maybe one misperception. That while vaccine was late, there was still plenty of antivirals in place that, you know, would have mitigated those tens of thousands of deaths. But, yeah, I think a major issue is, as several members have pointed out is, the vaccine was too little too late and that's not

something DoD can do anything about. It is something that the federal government is vitally interested in and has released -- I've forgotten now, was it about $3 billion in funding for cell culture and other techniques to try to accelerate the process of vaccine manufacture?

The problem is discovered in March, early April. It literally took six months, just as predicted -- well, they actually predicted it would be faster. But it takes six months to make the vaccine.

So I think, you know, from my perspective a couple of things are noteworthy. DoD was the first to pick up cases. It had the first draft plan, it was the first organization integrated into the federal work groups. The only one that sat on the ACIP. It had among the best outcomes. It had the highest immunization rates. It had, given the limitations that are imposed upon it, had, I think, some of the best distribution policies, procedures, and stockpiling. And perhaps most emblematic of

optimism for the future is what you just heard. DoD, in this instance, I think, could be characterized as a learning organization. They've done a look-back at what worked well and what didn't. Other groups haven't done that yet. And I think those will be helpful in going forward.

The other thing worth mentioning is that initially myself and then it transitioned to John. A member of our board, actually sat on -- I've forgotten the technical name of it, John. The --

DR. CLEMENTS: I'm sorry, John Clements. It's the VSAWG. It's the Vaccine Scientific Advisory Working Group for Safety of the H1N1 Vaccine.

DR. POLAND: And DoD is a major contributor to that safety database, primarily because of the extent -- the breadth and depth of the data capture that they do have.

Mike, do you want to make any additional comments in regard to this presentation?

COL KRUKAR: I can. We have participants who are part of the biz reg. And in

this working group, out of my office -- and I think that at the end of this month, I think, Dr. Clements, is when the preliminary findings may be presented.

DR. POLAND: So I think, you know, what we'll take back on the ID subcommittee is this very transparent set of lessons learned and work those in terms of what we might advise in terms of future improvements.

But all in all, given the constraints imposed on DoD, I think it was a job well done.

DR. SHAMOO: Well, thank you for informing me. I really appreciate it. You're more familiar with it, obviously.

DR. POLAND: Other comments? John.

DR. CLEMENTS: John Clements again. But I do think we were extraordinary fortunate here --

DR. POLAND: Oh, no question --

DR. CLEMENTS: -- in many respects. I mean, this turned out to be a virus that was close to one that was already in -- one that we could make relatively quickly in an FDA-approved

fashion. Had this been an H5 or something that was non-influenza, the challenge would have been horrendous because we would have been stuck with trying to produce a non-FDA approved vaccine in -- using systems that have not been thoroughly tested the way that influenza has. So I think there are a lot of things to learn here from what worked, but I think we should also be mindful that the challenges of something else crawling over the horizon are going to be huge if it turns out to be something other than influenza.

DR. POLAND: Yeah. Dr. Clements makes a good point for H5N1. While there was an FDA-approved vaccine, it induced what was thought to be protective titers of immunity in about 50 percent of people after 2 doses at least a month apart. Which would have, again, been a very different scenario than this one. So, indeed we were lucky.

COL HACHEY: In one of the -- recognizing that the vaccine was such an issue, in our ongoing funding request one of the things that

we want to do is to continue to stockpile vaccine like we have stockpiled the H5N1 vaccine. So that the leading threat is always represented on our shelf.

So, you know, again with H1N1, everybody was kind of taken by surprise. But if it does wind up being one of the frontrunners that we had been surveilling all along, then our goal is to have vaccine on the shelf so that we're not waiting for vaccine to be produced.

The other thing that we purchased is vaccine adjuvant. So even if we have a less than optimal match, at least the animal data and some limited human data suggest that if you take your H5N1 vaccine with a substantially lower dose, you only need one dose for good protection and, in fact, good cross-protection even if the strain isn't a terribly good match.

So, providing we have funding, we are hoping to be prepared as far as having a DoD-owned and controlled vaccine supply so that we can start an early immunization program if the need presents

itself.

DR. POLAND: Dr. Lednar, and then Colonel Krukar.

DR. LEDNAR: I think as we think about learning from this past experience and preparing for the next, I think there's an element of context that we should keep in mind.

Especially in Europe there is quite an active discussion right now that this pandemic was embellished, over described. Made into more than it was, in terms of severity and threat. I think there's plenty of objective evidence to say that that's not a fair assumption, but it is quite a drumbeat in Europe.

In the next pandemic there will be some who will remember that the push to get immunized against a pandemic threat turned out to be minor, and next time, therefore, why bother? Or a loss of trust in some public health authorities in terms of what they say.

So, what this may add up to is I think we may need better ways to communicate, more

persuasively communicate based on objective evidence, than we do right now. Because it's going to, in the future -- unless it's a very high case fatality threat, we're going to have a lot of people who are going to be disinclined to take advantage of the preventive intervention.

DR. POLAND: Colonel Krukar?

COL KRUKAR: And to help with the preventive intervention, TRICARE management activity has issued a rule whereby any DoD beneficiary can now receive the influenza -- the H1N1 or pneumococcal vaccine -- at no charge to the individual at any retail pharmacy location. Which means, any CVS or Walgreen's they can go out and get that now. They issued that last December.

DR. POLAND: Dr. Kaplan?

DR. KAPLAN: Perhaps I missed it, Wayne, but what's the current status of H5N1 this year?

COL HACHEY: It is still plugging along. The areas that have had human cases are still having to have -- still having human cases. It's not increasing, but it is pretty much a steady

state.

DR. KAPLAN: Geographically?

COL HACHEY: Same areas. It hasn't reached this hemisphere yet, but it is still active. Indonesia still has activity. Egypt has a fair amount of activity.

DR. POLAND: Dr. Ennis?

DR. ENNIS: I wanted to ask the question, Wayne, about the enhanced surveillance. So, the surveillance in the U.S. picked up those cases. Is the DoD going to support the enhanced surveillance activity in places such as Southeast Asia on a continuing basis?

COL HACHEY: Providing we continue to get funding.

DR. ENNIS: And I -- this question is probably for you, Greg. But if someone just mentioned that perhaps the DoD will have more control over purchasing vaccine and administering it in the future than it had last year. So is there a progress or is there some understanding that the DoD will return to being an independent

purchaser of vaccines and not be relying on directives from other government agencies?

COL HACHEY: The problem this time -- comparing this with H5N1. So with H5N1 we have been buying vaccine. It's ours, we use it however we want. With H1N1, it was a national buy by HHS. And that was a decision above the organizational chart that DoD sits. So, in circumstances like that, then I think -- and I can't speak for DoD leadership. But I would hope that given our past experience with H1N1, that some of our leadership may be more vocal as far as making sure that DoD has its own supply upfront.

But that's well out of anywhere I'll ever see in the organization.

DR. POLAND: Russ?

DR. LUEPKER: Yes. Colonel Hachey, you've -- this is Russell Luepker -- you said at least half a dozen times "if we get funding." I'm curious about what the cost of this program was, and why you feel that there's a threat to funding?

COL HACHEY: Well, over the past 5 years

we've been spending anywhere from -- depending on the year -- between $100 million and about $150 million for pandemic flu-related activities.

Of that, usually -- again, about $50 million goes toward surveillance with somewhere between $60- and $70 million for medical countermeasures.

That was true up until FY10. In FY10, our budget was cut from a little over $100 million to $50 million, with most of that -- actually all of that -- being earmarked for surveillance. Out of that $50 million we took back $8 million, and that's just to maintain our current stockpiles. To essentially pay the rent for our vaccines, for our antivirals, needles and syringes, ventilators. So just maintaining what we have, and no new expenditures.

We've received $160 million in supplemental funding. And with that we're paying for more personal protective equipment, enhanced surveillance, and replenishing our antiviral stockpile, and increasing the portfolio of our

antiviral stockpile.

For year-to-year requirements what we need is about $100 million. And right now we are budgeted again at $50 million for the next 5 years. One of the things that's being discussed -- almost as we speak, I believe tomorrow -- is whether to increase our baseline funding from that $50 million mark back to around $100 million plus inflation over the next 5 years. And that's the big "if" as far as funding.

So, the $50 million pretty much keeps the wheels turning a little slower than what they were doing before. And anything above that lets us essentially keep track of inflation and to also keep abreast of any new medication developments that come around that we might want to add to our portfolio.

DR. POLAND: Dr. Parkinson.

DR. PARKINSON: Yeah, Mike Parkinson. Very useful summary for me, Wayne. Because as someone who's not a primary influenza expert, sometimes information overload -- which was not

what we had. But, you know, you get a lot of static noise. And what we probably need, if it's not already been done, Dr. Poland, is to crystallize the absolute crystal clear message of this hot wash to Secretary Gates and through the ASD(HA).

Namely, that had we had a real threat, despite all the firsts you mentioned -- but they should be noted -- we would have missed the mark. Because we over-relied on a government distribution system that, historically, we now have real data. And would suggest that we immediately assure that that's our number one job, is the fitness and the readiness of the force. To do what we have to do. And this is a major concern.

I wouldn't, obviously, get into funding levels. That's not our job. But if it's that crystal -- Dr. Ennis, I appreciate your comments -- we just need to put it in simple text. And maybe it's been done, but it's not really in a briefing, per se. It's in a short, factual

summary --

DR. POLAND: I could see that being very useful.

DR. PARKINSON: -- to the Secretary.

DR. POLAND: Yeah.

DR. WALKER: Well, not only will the next one likely be much worse than this, but this one's much worse than many of us think it was, if you look at such figures as years of life lost. Because the fact that it attacked younger individuals.

DR. POLAND: Right. Okay. I think we have completed our duties for today. Ms. Bader, do you want to give some admin remarks and we'll be dismissed?

MS. BADER: All right. Sounds great. For board members, ex officio members, service liaisons, speakers, and invited guests, tomorrow morning, again, we will start off with an admin session at 8:00 in the morning. Registration starts at 7:30. We'll have a session from 8:00 to 9:00, and then the open session will begin at

9:00.

For those of you joining us for dinner tonight, please convene in the lobby by 6:00 p.m. The group dinner is scheduled for 6:30 at Restaurant 3 located at 2950 Clarendon Boulevard in Arlington, for those who will be driving. It's only, again, about a mile and a half away. And for those who will be leaving and taking the Metro after this meeting, it's right across the street in Roslyn down Fort Myer Avenue.

So, again, we will reconvene the open session tomorrow morning at 9:00 a.m. For folks that will attend the administrative session, 8:00 next door, just like we started this morning.

We're going to adjust the agenda for tomorrow afternoon, and I'd like to ask that Colonel Mott, Lieutenant Colonel Gould, and Captain Naito be available to brief at 11:00. We have an administrative session planned for lunch, so please -- I know many of you if you're not doing PT prior to your flight and you want to head out early, if you could just try to make your

plane reservation for after the lunchtime that would be greatly appreciated.

(Whereupon, at 3:57 p.m., the PROCEEDINGS were adjourned.)

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CERTIFICATE OF NOTARY PUBLIC

DISTRICT OF COLUMBIA

I, Christine Allen, notary public in and for the District of Columbia, do hereby certify that the forgoing PROCEEDING was duly recorded and thereafter reduced to print under my direction; that the witnesses were sworn to tell the truth under penalty of perjury; that said transcript is a true record of the testimony given by witnesses; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this proceeding was called; and, furthermore, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.

Notary Public, in and for the District of Columbia

My Commission Expires: January 14, 2013